UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION **This document relates to:** *County of Trumbull, Ohio v. Purdue Pharma, L.P. et al.*, Case No. 18-op-45079; *The County of Lake, Ohio v. Purdue Pharma L.P., et al.*, Case No. 18-op-45032	**MDL No. 2804** **Case No. 1:17-md-2804** **Judge Dan Aaron Polster**

CASE TRACK THREE PLAINTIFFS' MOTION FOR LEAVE TO FILE AMENDED COMPLAINTS

EXHIBIT B

Respectfully submitted,

/s/ Paul J. Hanly, Jr.
Paul J. Hanly, Jr.
SIMMONS HANLY CONROY
112 Madison Avenue, 7th Floor
New York, NY 10016
(212) 784-6400
(212) 213-5949 (fax)
phanly@simmonsfirm.com

/s/ Joseph F. Rice
Joseph F. Rice
MOTLEY RICE LLC
28 Bridgeside Blvd.
Mt. Pleasant, SC 29464
(843) 216-9000
(843) 216-9290 (Fax)
jrice@motleyrice.com

/s/ Paul T. Farrell, Jr.
Paul T. Farrell, Jr.
FARRELL LAW
422 Ninth St., 3rd Floor
Huntington, WV 25701
(304) 654-8281
paul@farrell.law

Plaintiffs' Co-Lead Counsel
/s/ Peter H. Weinberger
Peter H. Weinberger
SPANGENBERG SHIBLEY & LIBER 1001 Lakeside Avenue East, Suite 1700 Cleveland, OH 44114
(216) 696-3232
(216) 696-3924 (Fax)
pweinberger@spanglaw.com

Plaintiffs' Liaison Counsel

Hunter J. Shkolnik
NAPOLI SHKOLNIK
360 Lexington Ave., 11th Floor
New York, NY 10017
(212) 397-1000
(646) 843-7603 (Fax)
hunter@napolilaw.com

Counsel for Plaintiffs Lake County and Trumbull County, Ohio

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 27th day of May, 2020, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF System. Copies will be served upon counsel of record via email.

/s/Linda Singer
Linda Singer

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION

This document relates to:
Case No. 18-op-45079

THE COUNTY OF LAKE,

Plaintiff,

vs.

CVS HEALTH CORPORATION; CVS INDIANA L.L.C.; CVS RX SERVICES, INC.; CVS TN DISTRIBUTION, LLC; CVS PHARMACY, INC.; OMNICARE DISTRIBUTION CENTER LLC; OHIO CVS STORES, LLC; WALGREEN CO.; WALGREENS BOOTS ALLIANCE, INC.; WALGREEN EASTERN CO., INC.; RITE AID CORP.; RITE AID HDQTRS. CORP.; ECKERD CORPORATION D/B/A RITE AID LIVERPOOL DISTRIBUTION CENTER; RITE AID OF OHIO, INC.; RITE AID OF MARYLAND, INC.; HBC SERVICE COMPANY; GIANT EAGLE, INC.; WALMART INC. F/K/A WAL-MART STORES, INC.; WAL-MART STORES EAST, LP; WSE MANAGEMENT, LLC; WSE INVESTMENT LLC; AND WAL-MART STORES EAST, INC.,

Defendants.

MDL No. 2804

Case No. 17-md-2804

Judge Dan Aaron Polster

SUPPLEMENTAL AND AMENDED ALLEGATIONS TO BE ADDED TO "SHORT FORM FOR SUPPLEMENTING COMPLAINT AND AMENDING DEFENDANTS AND JURY DEMAND"

CONFIDENTIAL: FILED UNDER SEAL

TABLE OF CONTENTS

Page

TABLE OF CONTENTS
(continued)

Page

TABLE OF CONTENTS
(continued)

Page

TABLE OF CONTENTS
(continued)

Page

TABLE OF CONTENTS
(continued)

Page

1. Plaintiff the County of Lake, Ohio (the "County" or "Plaintiff") brings this action to prevent future harm and to redress past wrongs, against Defendants: CVS Health Corporation; CVS Indiana L.L.C.; CVS Rx Services, Inc.; CVS TN Distribution, LLC; CVS Pharmacy, Inc.; Ohio CVS Stores, LLC; Walgreen Co.; Walgreens Boots Alliance, Inc.; Walgreen Eastern Co., Inc.; Rite Aid Corp.; Rite Aid Hdqtrs. Corp.; Rite Aid of Ohio, Inc.; Eckerd Corporation d/b/a Rite Aid Liverpool Distribution Center; Rite Aid of Maryland, Inc.; HBC Service Company; Giant Eagle, Inc.; Walmart Inc. f/k/a Wal-Mart Stores, Inc., and Management, LLC; WSE Investment LLC; and Wal-Mart Stores East, Inc. (collectively, the "Chain Pharmacies" or "Defendants").[1] Plaintiff seeks to hold accountable the Chain Pharmacies that reaped enormous financial rewards by refusing to monitor and restrict the improper sale and distribution of opioids and abate the opioid epidemic in the County.[2]

[IN ADDITION TO THE ALLEGATIONS SET FORTH HEREIN, THE COUNTY EXPRESSLY ADOPTS AND INCORPORATES BY REFERENCE THE ALLEGATIONS AND CLAIMS SET FORTH IN ITS COMPLAINT AND "SHORT FORM FOR SUPPLEMENTING COMPLAINT AND AMENDING DEFENDANTS AND JURY DEMAND," ("SHORT FORM COMPLAINT") INCLUDING ALL CLAIMS AND ALLEGATIONS AGAINST OTHER DEFENDANTS NAMED IN THAT SHORT FORM COMPLAINT.]

[1] Consistent with this Court's direction in the Order Regarding Track Three (Doc. 3282), the County understands that only claims against pharmacy defendants for public nuisance will proceed in Track Three and is not adding any allegations against other defendants at this time. The County reserves the right to amend such allegations in the future if the stay of claims against other parties is lifted.

[2] The following are newly added Defendants: CVS Indiana L.L.C.; CVS Rx Services, Inc.; CVS TN Distribution, LLC; CVS Pharmacy, Inc.; Ohio CVS Stores, LLC; Rite Aid Corp.; Rite Aid Hdqtrs. Corp.; Rite Aid of Ohio, Inc.; Eckerd Corporation d/b/a Rite Aid Liverpool Distribution Center; Rite Aid of Maryland, Inc.; Giant Eagle, Inc.; Walmart Inc. f/k/a Wal-Mart Stores, Inc., and Management, LLC; WSE Investment LLC; and Wal-Mart Stores East, Inc.

INTRODUCTION

2. This case arises from the worst man-made epidemic in modern medical history—the misuse, abuse, and over-prescription of opioids.

3. By now, most Americans have been affected, either directly or indirectly, by the opioid disaster. This crisis arose not only from the opioid manufacturers' deliberate marketing strategy, but from distributors' and pharmacies' equally deliberate efforts to evade restrictions on opioid distribution and dispensing. These distributors and pharmacies acted without regard for the lives that would be trammeled in pursuit of profit.

4. Since the push to expand prescription opioid use began in the late 1990s, the death toll has steadily climbed, with no sign of slowing. The number of opioid overdoses in the United States rose from 8,000 in 1999 to over 20,000 in 2009, and over 33,000 in 2015. In the twelve months that ended in September 2017, opioid overdoses claimed 45,000 lives.

5. From 1999 through 2016, more than 350,000 people died from an overdose involving any opioids. Well over half of those deaths—over 200,000 people—involved opioids prescribed by doctors to treat pain. These opioids include brand-name prescription medications like OxyContin, Opana ER, Vicodin, Subsys, and Duragesic, as well as generics like oxycodone, hydrocodone, and fentanyl.

6. Most of the overdoses from non-prescription opioids are also directly related to prescription pills. Many opioid users, having become addicted to but no longer able to obtain prescription opioids, have turned to heroin. According to the American Society of Addiction Medicine, 80% of people who initiated heroin use in the past decade started with prescription painkillers—which, at the molecular level and in their effect, closely resemble heroin. In fact, people who are addicted to prescription painkillers are 40 times more likely to become addicted to

heroin, and the CDC identified addiction to prescription pain medication as the strongest risk factor for heroin addiction.

7. As a result, in part, of the proliferation of opioid pharmaceuticals between the late 1990s and 2015, the life expectancy for Americans decreased for the first time in recorded history. Drug overdoses are now the leading cause of death for Americans under 50.

8. In the words of Robert Anderson, who oversees death statistics at the Centers for Disease Control and Prevention, "I don't think we've ever seen anything like this. Certainly not in modern times." On October 27, 2017, the President declared the opioid epidemic a public health emergency.

9. This suit takes aim at a primary cause of the opioid crisis: a supply chain scheme, pursuant to which distributors and pharmacies failed to design and operate systems to identify suspicious orders of prescription opioids, maintain effective controls against diversion, and halt suspicious orders when they were identified, and instead actively contributed to the oversupply of such drugs and fueled an illegal secondary market.

10. Defendants have contributed substantially to the opioid crisis by selling and distributing far greater quantities of prescription opioids than they know could be necessary for legitimate medical uses, while failing to report, and to take steps to halt suspicious orders and sales, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market.

11. In 2014, almost two million Americas were addicted to prescription opioids and another 600,000 to heroin. From 1999 to 2015, more than 183,000 people died in the U.S. from overdoses related to prescription opioids—more than the number of Americans who died in the Vietnam War. From 1999 to 2016, more than 200,000 people died in the U.S. from overdoses

related to prescription opioids. Overdose deaths involving prescription opioids were five times higher in 2017 than 1999.

12. As millions became addicted to opioids, "pill mills," often styled as "pain clinics," sprouted nationwide and rogue prescribers stepped in to supply prescriptions for non-medical use. These pill mills, typically under the auspices of licensed medical professionals, issue high volumes of opioid prescriptions under the guise of medical treatment. Prescription opioid pill mills and rogue prescribers cannot channel opioids for illicit use without at least the tacit support and willful blindness of the Defendants, if not their knowing support.

13. As a direct and foreseeable result of Defendants' conduct, cities and counties across the nation, including Plaintiffs, are now swept up in what the Centers for Disease Control ("CDC") has called a "public health epidemic" and what the U.S. Surgeon General has deemed an "urgent health crisis."[3] The increased volume of opioid prescribing, not all of which is for legitimate use, correlates directly to skyrocketing addiction, overdose and death; black markets for diverted prescriptions opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire or simply could not afford prescription opioids.

14. This explosion in opioid use and Defendants' profits has come at the expense of patients and residents and has caused ongoing harm and damages to Lake County. As the then CDC director concluded: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[4]

---

[3] *Examining the Growing Problems of Prescription Drug and Heroin Abuse,* Ctrs. For Disease Control and Prevention (Apr. 29, 2014), http://www,cdc,give.washington/testimony/2014/t20140429.htm; *see also,* Letter from Vivek H. Murthy, Surgeon General, Tide RX (Aug. 2016), http://turnthetiderx.org.

[4] *Id.*

15. Defendants' conduct in promoting opioid use, addiction, abuse, overdose and death has had severe and far-reaching public health, social services, and criminal justice consequences, including the fueling of addiction and overdose from illicit drugs such as heroin. The costs are borne by Plaintiff and other governmental entities. These necessary and costly responses to the opioid crisis include the handling of emergency responses to overdoses, providing addiction treatment, handling opioid-related investigations, arrests, adjudications, and incarceration, treating opioid-addicted newborns in neonatal intensive care units, burying the dead, and placing thousands of children in foster care placements, among others.

16. The burdens imposed on Plaintiff are not the normal or typical burdens of government programs and services. Rather, these are extraordinary costs and losses that are related directly to Defendants' illegal actions. The Defendants' conduct has created a public nuisance and a blight. Governmental entities, and the services they provide their citizens, have been strained to the breaking point by this public health crisis.

17. Defendants have not changed their ways or corrected their past misconduct but instead are continuing to fuel the crisis and perpetuate the public nuisance.

18. Within the next hour, six Americans will die from opioid overdoses; two babies will be born addicted to opioids and begin to go through withdrawal.

19. Plaintiff brings this suit to bring the devastating march of this epidemic to a halt and to hold Defendants responsible for the crisis they caused.

JURISDICTION AND VENUE

20. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 because this action includes claims under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq.*, which raise a federal question. This Court has supplemental

jurisdiction over the County's state-law claims under 28 U.S.C. § 1367 because those claims are so related to the RICO claim as to form part of the same case or controversy.

21. This Court has personal jurisdiction over all Defendants under R.C. 2307.382 because the causes of action alleged in this Complaint arise out of each Defendants' transacting business in Ohio, contracting to supply services or goods in this state, causing tortious injury by an act or omission in this state, and because the Defendants regularly do or solicit business or engage in a persistent course of conduct or deriving substantial revenue from goods used or consumed or services rendered in this state. Defendants have purposefully directed their actions towards Ohio and/or have the requisite minimum contacts with Ohio to satisfy any statutory or constitutional requirements for personal jurisdiction.

22. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b)(2) in that a substantial part of the events or omissions giving rise to the claim occurred in the Northern District of Ohio. Venue is also proper under 18 U.S.C. § 1965(a) because Defendants reside, are found, have agents, or transact their affairs in this district.

PARTIES

I. PLAINTIFF

23. The County of Lake, Ohio ("the County") is a County organized under the laws of the State of Ohio with a population of approximately 230,000. Plaintiff provides a wide range of services on behalf of its residents, including services for families and children, public health, public assistance, law enforcement, and emergency care.

II. DEFENDANTS[5]

1. CVS.

24. Defendant CVS Health Corporation ("CVS Health") is a Delaware corporation with its principal place of business in Rhode Island. CVS Health, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor and also operates retail stores, including in and around Plaintiff's geographical area, that sell prescription medicines, including opioids.

25. Defendant CVS Indiana L.L.C. is an Indiana limited liability company with its principal place of business in Indianapolis, Indiana. Defendant CVS Rx Services, Inc. is a New York corporation with its principal place of business in Chemung, NY. Defendant CVS TN Distribution, LLC is a Tennessee corporation with its principal place of business in Knoxville, TN.

26. Defendant CVS Pharmacy, Inc. is a Rhode Island corporation with its principal place of business in Woonsocket, Rhode Island. CVS Pharmacy, Inc. is a wholly owned subsidiary of CVS Health. Defendant CVS Pharmacy, Inc. is both a DEA registered "distributor"[6] and a DEA registered "dispenser"[7] of prescription opioids and is registered to do business in Ohio. Defendant Ohio CVS Stores, LLC is an Ohio corporation with its principal place of business in Woonsocket, Rhode Island, and is registered to do business in Ohio.

---

[5] The County has made its best efforts, based on the information available, to identify all of the corporate entities with responsibilities related to the sale and distribution of opioids in or affecting the County. If information that becomes available to the County alters its understanding or discloses additional entities, the County reserves the right to seek to join any such entities as defendants. Furthermore, the County recognizes that corporate entities affiliated with the Defendants may possess discoverable information relevant to the County's claims, even though those entities have not been named as defendants. The County reserves the right to seek all information relevant to these claims.

[6] 21 U.S.C. §802(11) and §822(a)(1).

[7] 21 U.S.C. §802(10) and §822(a)(2).

27. Defendant Omnicare Distribution Center LLC is a Delaware corporation with its principal place of business in Ohio. Omnicare Distribution Center LLC, a CVS Health company, portrays itself as an industry leading long-term care pharmacy services provider focused on supporting community residents

28. Defendants CVS Health Corporation, CVS Indiana L.L.C., CVS Rx Services, Inc., CVS TN Distribution, LLC, CVS Pharmacy, Inc., Omnicare Distribution Center LLC, and Ohio CVS Stores, LLC are collectively referred to as "CVS." CVS conducts business as a licensed wholesale distributor and dispenser. At all times relevant to this Complaint, CVS distributed and/or dispensed prescription opioids throughout the United States, including in Ohio and Lake County specifically.

2. Walgreens.

29. Defendant Walgreen Co. acted as a retail pharmacy in the United States, until Walgreen Co. completed the acquisition of Alliance Boots, a British pharmacy giant, in 2014. After this acquisition, the company simply became Walgreens Boots Alliance, Inc. traded on NASDAQ under the symbol WBA.

30. Defendant Walgreens Boots Alliance, Inc. is a Delaware corporation that describes itself as the successor of Walgreen Co., an Illinois corporation. Both Walgreens Boots Alliance, Inc. and Walgreen Co. are have their principal place of business Illinois.

31. Walgreen Co. is portrayed as a subsidiary of Walgreens Boots Alliance, Inc. and does business under the trade name Walgreens.

32. During the relevant time period, Walgreens self-distributed opioids and cocktail drugs to its own pharmacies from distribution centers which it owned and operated. At least between 2006 and 2014, Walgreens distributed opioids and cocktail drugs from its distribution

centers, including those in Jupiter, Florida, Perrysburg, Ohio, and Mount Vernon, Illinois to Walgreens retail pharmacies located in Ohio, including in Lake County.

33. Defendant Walgreen Eastern Co., Inc. is a New York corporation with its principal place of business in Deerfield, Illinois. Walgreen Eastern Co., Inc. is a subsidiary of Walgreens Boots Alliance, Inc.

34. Defendants Walgreens Boots Alliance, Inc., Walgreen Co., and Walgreen Eastern Co., Inc. are collectively referred to as "Walgreens."

35. Walgreens conducted business as a licensed wholesale distributor, as described above. Throughout the relevant time period, and as further alleged below, Walgreens entities also owned and operated pharmacies in the County. At all times relevant to this Complaint, Walgreens distributed and/or sold prescription opioids throughout the United States, including in Ohio and Lake County specifically.

36. The DEA distribution registrations for Walgreens's controlled substances distribution centers that distributed opioids and cocktail drugs into Lake County were held by Walgreens Co. and/or Walgreens Eastern Co.

37. Walgreens Co. created, implemented, and had the power to enforce policies, practices, and training regarding distribution and sales in all Walgreens distribution and pharmacy sales operations.

38. The DEA dispensing registrations for Walgreens's pharmacies in Lake County were held by Walgreens Co., which operated each pharmacy as a "d/b/a/" entity.

39. Expanding its chain pharmacy operations, Walgreens also acquired a number of former Rite Aid stores, including in the County. Walgreens is liable as a successor for these stores' prior conduct, as well as for its own operations.

3. Rite Aid.

40. Defendant Rite Aid Corporation is a Delaware corporation with its principal office located in Camp Hill, Pennsylvania.

41. Defendant Rite Aid Hdqtrs. Corp. is a Delaware corporation with its principal office located in Camp Hill, Pennsylvania. Defendant Rite Aid Hdqtrs. Corp. and Defendant Rite Aid Corporation, by and through their various DEA registered subsidiaries and affiliated entities, conduct business as licensed wholesale distributors and pharmacy operators.

42. Defendant Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc. is a subsidiary of Rite Aid Corporation and is itself a Maryland corporation with its principal office located in Camp Hill, Pennsylvania.

43. Defendant Eckerd Corporation d/b/a Rite Aid Liverpool Distribution Center is a subsidiary of Rite Aid Corporation and is itself a Delaware corporation with its principal office located in Camp Hill, Pennsylvania. At all times relevant to this Complaint, Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc. and Eckerd Corporation d/b/a Rite Aid Liverpool Distribution Center distributed prescription opioids throughout the United States, including in Ohio and Lake County specifically.

44. During the relevant time period, and as further alleged below, Rite Aid entities also owned and operated pharmacies in the County through Defendant Rite Aid of Ohio, Inc. Defendant Rite Aid of Ohio, Inc. is an Ohio corporation with its principal place of business in Ohio. Rite Aid of Ohio, Inc. was in the business of holding and operating retail pharmacies in Ohio, including in Lake County, on behalf of its parent company Rite Aid Corporation. Rite Aid of Ohio, Inc. orders of controlled substances came from Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc. and Eckerd Corporation d/b/a Rite Aid Liverpool Distribution Center and other wholesalers. These controlled substances are distributed and dispensed according

to practices and procedures established by Rite Aid Corporation and Rite Aid Headquarters Corporation.

45. Defendants Rite Aid Corporation, Rite Aid Hdqtrs. Corp., Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc., Eckerd Corporation d/b/a Rite Aid Liverpool Distribution Center, and Rite Aid of Ohio, Inc. are collectively referred to as "Rite Aid."

46. Rite Aid, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. Rite Aid also operates retail stores, including in and around Plaintiff's geographical area that sell prescription medicines, including opioids.

47. At all times relevant to this Complaint, Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc. distributed prescription opioids throughout the United States, including in Ohio and Lake County specifically.

4. Walmart.

48. Defendant Walmart Inc., formerly known as Wal-Mart Stores, Inc., is a Delaware corporation with its principal place of business in Bentonville, Arkansas.

49. Defendant Wal-Mart Stores East, LP is a Delaware limited partnership with its principle place of business in Arkansas.

50. Defendant WSE Management, LLC, is a Delaware limited liability company, and owns one percent of Wal-Mart Stores East, LP.

51. Defendant WSE Investment, LLC, is a Delaware limited liability company, and a ninety-nine percent of Wal-Mart Stores East, LP.

52. The sole owner of both WSE Management, LLC and WSE Investment, LLC is Walmart-Stores East Inc., an Arkansas corporation.

53. The sole shareholder of Wal-Mart Stores East, Inc. is Walmart Inc., f/k/a Wal-Mart Stores, Inc.

54. Defendants Walmart Inc., f/k/a Wal-Mart Stores, Inc., Wal-Mart Stores East, LP, WSE Management, LLC, WSE Investment LLC, Wal-Mart Stores East, Inc. are collectively referred to as "Walmart."

55. Walmart, through its various DEA registrant subsidiaries and affiliated entities, conducts business as a registered wholesale distributor and as a pharmacy.

56. At all times relevant to this Complaint, Walmart distributed and sold prescription opioids throughout the United States, including in Ohio and Lake County specifically.

5. Giant Eagle.

57. Defendant HBC Service Company ("HBC") is an operating division of Defendant Giant Eagle, Inc. HBC operated as a licensed wholesale distributor wholesaler in Ohio, licensed by the State of Ohio Board of Pharmacy. Giant Eagle, Inc. is a Pennsylvania corporation with its principal place of business in Washington, Pennsylvania. At all times relevant to this Complaint, HBC distributed and Giant Eagle, Inc. sold prescription opioids in Ohio and Lake County specifically. HBC, Giant Eagle, and related entities are collectively referred to as "Giant Eagle." From 2016 to the present, Giant Eagle also distributed prescription opioids through its GERXDC distribution center, which it then sold in Giant Eagle pharmacies.

58. Collectively, Defendants CVS, Rite Aid, Walgreens, Walmart, and Giant Eagle are referred to as "Chain Pharmacies."

59. Defendants include the above referenced entities as well as their predecessors, successors, affiliates, subsidiaries, partnerships and divisions to the extent that they are engaged in the manufacture, promotion, distribution, sale, and/or dispensing of opioids.

A. Agency and Authority

60. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority.

61. Plaintiff alleges that the corporate parents named as defendants in this Complaint are liable as a result of their own actions and obligations in distributing and selling opioids, and not solely because of their vicarious responsibility for the actions of their pharmacy stores.

FACTUAL ALLEGATIONS

I. FACTS COMMON TO ALL CLAIMS[8]

A. Opioids and Their Effects

62. The term "opioid" refers to a class of drugs that bind with opioid receptors in the brain and includes natural, synthetic, and semi-synthetic opioids. Natural opioids are derived from the opium poppy. Generally used to treat pain, opioids produce multiple effects on the human body, the most significant of which are analgesia, euphoria, and respiratory depression.

63. The medicinal properties of opioids have been recognized for millennia—as well as their potential for abuse and addiction. The opium poppy contains various opium alkaloids, three of which are used in the pharmaceutical industry today: morphine, codeine, and thebaine. Early use of opium in Western medicine was with a tincture of opium and alcohol called laudanum,

[8] The allegations in this complaint are made upon information and belief, including upon information immediately available to plaintiffs from the ARCOS database upon their initial and intensive review. Plaintiff reserves the right to seek leave to amend or correct this Complaint based upon further analysis of the ARCOS, IMS Health, and other data and upon further investigation and discovery.

which contains all of the opium alkaloids and is still available by prescription today. Chemists first isolated the morphine and codeine alkaloids in the early 1800s.

64. In 1827, the pharmaceutical company Merck began large-scale production and commercial marketing of morphine. During the American Civil War, field medics commonly used morphine, laudanum, and opium pills to treat the wounded, and many veterans were left with morphine addictions. By 1900, an estimated 300,000 people were addicted to opioids in the United States, and many doctors prescribed opioids solely to prevent their patients from suffering withdrawal symptoms. The nation's first Opium Commissioner, Hamilton Wright, remarked in 1911, "The habit has this nation in its grip to an astonishing extent. Our prisons and our hospitals are full of victims of it, it has robbed ten thousand businessmen of moral sense and made them beasts who prey upon their fellows . . . it has become one of the most fertile causes of unhappiness and sin in the United States."[9]

65. In 1898, Bayer Pharmaceutical Company began marketing diacetylmorphine (obtained from acetylation of morphine) under the trade name "Heroin." Bayer advertised heroin as a non-addictive cough and cold remedy suitable for children, but as its addictive nature became clear, heroin distribution in the U.S. was limited to prescription only in 1914 and then banned altogether a decade later.

66. Although heroin and opium became classified as illicit drugs, there is little difference between them and prescription opioids. Prescription opioids are synthesized from the

[9] Nick Miroff, *From Teddy Roosevelt to Trump: How Drug Companies Triggered an Opioid Crisis a Century Ago*, The Wash. Post (Oct. 17, 2017), https://www.washingtonpost.com/news/retropolis/wp/2017/09/29/the-greatest-drug-fiends-in-the-world-an-american-opioid-crisis-in-1908/?utm_term=.7832633fd7ca.

same plant as heroin, have similar molecular structures, and bind to the same receptors in the human brain.

67. Due to concerns about their addictive properties, prescription opioids have usually been regulated at the federal level as Schedule II controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970.

68. Medical professionals describe the strength of various opioids in terms of morphine milligram equivalents ("MME"). According to the CDC, doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and one study found that patients who died of opioid overdose were prescribed an average of 98 MME/day.

69. Patients develop tolerance to the analgesic effect of opioids relatively quickly. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same perceived level of pain reduction. The same is true of the euphoric effects of opioids—the "high." However, opioids depress respiration, and at very high doses can and often do arrest respiration altogether. At higher doses, the effects of withdrawal are more severe. Long-term opioid use can also cause hyperalgesia, a heightened sensitivity to pain.

70. Discontinuing opioids after more than just a few weeks will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

B. Defendants' Conduct Created an Abatable Public Nuisance

71. As alleged throughout this Complaint, Defendants' conduct created a public health crisis and a public nuisance.

72. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated by, inter alia, (a) providing addiction treatment to patients who are already addicted to opioids; and (b) making naloxone widely available so that overdoses are less frequently fatal.

73. Defendants have the ability to act to abate the public nuisance, and the law recognizes that they are uniquely well positioned to do so. All companies in the supply chain of a controlled substance are primarily responsible for ensuring that such drugs are only distributed and sold to appropriate patients and not diverted. These responsibilities exist independent of any Food and Drug Administration ("FDA") or Drug Enforcement Administration ("DEA") regulation, to ensure that their products and practices meet both federal and state laws and regulations. As registered distributors and dispensers of controlled substances, Defendants are placed in a position of special trust and responsibility and are uniquely positioned, based on their knowledge of prescribers and orders, to act as a key line of defense. Defendants, however, instead abused their position of special trust and responsibility within the closed system of opioid distribution and dispensing and fostered a black market for prescription opioids.

C. Defendants Deliberately Disregarded Their Duties to Maintain Effective Controls Against Diversion.

1. The Chain Pharmacies Were on Notice of and Contributed to Illegal Diversion of Prescription Opioids.

74. Retail pharmacy chains earned enormous profits by flooding the country with prescription opioids. They were keenly aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and retail sellers of opioids. Yet, instead of taking any meaningful action to stem the flow of opioids into communities, they continued to participate in the oversupply and profit from it.

75. Each of the Chain Pharmacies does substantial business across the United States. This business includes the distribution and sale of prescription opioids.

76. Statewide ARCOS data confirms that the Chain Pharmacies distributed and dispensed substantial quantities of prescription opioids, including fentanyl, hydrocodone, and oxycodone in the County. In addition, they distributed and dispensed substantial quantities of prescription opioids in other states, and these drugs were diverted from these other states to the County. The Chain Pharmacies failed to take meaningful action to stop this diversion despite their knowledge of it, and thus contributed substantially to the diversion problem.

77. The Chain Pharmacies developed and maintained extensive data on opioids they distributed and dispensed. Through this data, Chain Pharmacies had direct knowledge of patterns and instances of improper distribution, prescribing, sale, and use of prescription opioids in communities throughout the country, and in the County in particular. They used the data to evaluate their own sales activities and workforce. The Chain Pharmacies also provided data regarding, *inter alia*, individual doctors to drug companies, which targeted those prescribers with their marketing, in exchange for rebates or other forms of consideration. The Chain Pharmacies' data is a valuable resource that they could and should have used to help stop diversion, but they failed to do so. Defendants facilitated the supply of far more opioids that could have been justified to serve a legitimate market. The failure of the Defendants to maintain effective controls, and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious, as well as to maintain effective policies and procedures to guard against diversion from their retail stores, breached both their statutory and common law duties.

78. For over a decade, Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously

increasing the volume of opioids they sold. However, Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers.

79. Defendants are all required to register as distributors or dispensers pursuant to 21 U.S.C. § 823 and 21 C.F.R. §§ 1301.11, 1301.74.

80. Each participant in the supply chain of opioid distribution, including the Chain Pharmacies, is responsible for preventing diversion of prescription opioids into the illegal market by, among other things, monitoring, and reporting suspicious activity.

81. According to the CDC, opioid prescriptions, as measured by number of prescriptions and MME per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. Not all of these prescriptions were legitimate. Yet, Defendants systemically ignored red flags that they were fueling a black market, and failed to maintain effective controls against diversion at both the wholesale and pharmacy level. Instead, they put profits over the public health and safety. Despite their legal obligations as registrants under the CSA, the Chain Pharmacies allowed widespread diversion to occur—and they did so knowingly.

82. Upon information and belief, this problem was compounded by the Chain Pharmacies' failure to adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into whether a prescription is legitimate and what measures and/or actions to take when a prescription is identified as potentially illegitimate.

83. Upon information and belief, the Chain Pharmacies also failed to put in place effective policies and procedures to prevent their stores from facilitating diversion and selling into a black market, and to conduct adequate internal or external reviews of their opioid sales to identify

patterns regarding prescriptions that should not have been filled, or if they conducted such reviews, they failed to take any meaningful action as a result.

84. Upon information and belief, even where Chain Pharmacies enacted policies and procedures to prevent stores from facilitating diversion and selling into a black market, such policies were merely window-dressing and were not employed in any meaningful way.

85. Upon information and belief, the Chain Pharmacies also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions. Instead, Chain Pharmacies put in place policies that required and rewarded speed and volume over the safety and care necessary to ensure that narcotics were distributed and sold lawfully. Defendants consistently put profits over safety in their distribution and sale of prescription opioids.

86. The Chain Pharmacies were, or should have been, fully aware that the quantity of opioids being distributed and dispensed by them was untenable, and in many areas patently absurd; yet, they did not take meaningful action to investigate or to ensure that they were complying with their duties and obligations under the law with regard to controlled substances.

2. Defendants Have a Duty to Report Suspicious Orders and Not to Ship Those Orders Unless Due Diligence Disproves Their Suspicions.

87. Multiple sources impose duties on the Defendants to report suspicious orders and further to not ship those orders unless due diligence disproves those suspicions.

88. First, under the common law, Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances. By flooding Ohio, and the County, with more opioids than could be used for legitimate medical purposes, by filling and failing to report orders that they knew or should have realized were likely being diverted for illicit uses, and by failing to maintain

effective controls against diversion from their retail stores, Defendants breached that duty and both created and failed to prevent a foreseeable risk of harm.

89. Second, each of the Defendants assumed a duty, when speaking publicly about opioids and their efforts to combat diversion, to speak accurately and truthfully.

90. Third, distributors and chains pharmacies are required to register with the DEA to distribute and/or dispense controlled substances. *See* 21 U.S.C. § 823(a)-(b), (e); 28 C.F.R. § 0.100; 28 C.F.R. § 1301.71. As registrants, Defendants were required to "maint[ain] . . . effective controls against diversion" and to "design and operate a system to disclose . . . suspicious orders of controlled substances." 21 U.S.C. § 823(a)-(b); 21 C.F.R. § 1301.74. Defendants were further required to take steps to halt suspicious orders. Defendants violated their obligations under federal law.

91. Under the federal Controlled Substances Act ("CSA") and Ohio controlled-substances laws, they likewise were required to design and operate effective systems to guard against diversion. *See, e.g.*, 21 U.S.C. § 823; 28 C.F.R. § 1301.71. Federal regulations issued under the CSA also mandate that all registrants "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). Defendants also have independent duties under Ohio law. The Ohio Administrative Code imposes obligations and duties upon "licensees" and "registrants," to "provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs." O.A.C. § 4729-9-05(A). These duties extend to Defendants as distributors and pharmacies. The Chain Pharmacies, like other distributors, are registrants under the CSA. 21 C.F.R. § 1301.11.

92. Further, under the CSA, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." *See* 21

C.F.R. § 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." Thus, regardless of whether they are registrants, all dispensers must ensure that prescriptions of controlled substances are "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). The DEA has recognized that "as dispensers of controlled substances, pharmacists and pharmacy employees are often the last line of defense in preventing diversion."[10]

93. Under the CSA, the duty to prevent diversion lies with the Chain Pharmacies, not the individual pharmacist. As such, although it acts through its agents, the pharmacy is ultimately responsible to prevent diversion, as described above.[11] Further, the obligations under the controlled-substances laws extend to any entity selling prescription opioids, whether it is the registration-holder or not.

94. Thus, in addition to their duties as distributors, the Chain Pharmacies also had a duty to design and implement systems to prevent diversion of controlled substances in their retail pharmacy operations. The Chain Pharmacies had the ability, and the obligation, to look for these

[10]2012 Dear Registrant letter to pharmacy registrants, http://ppsconline.com/articles/2012/FL_PDAC.pdf

[11] *The Medicine Shoppe; Decision and Order*, 79 FR 59504, 59515 (DEA Oct. 2, 2014) (emphasis added); *see also Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*; Decision and Order, 77 FR 62316-01 ("When considering whether a pharmacy has violated its corresponding responsibility, the Agency considers whether the entity, not the pharmacist, can be charged with the requisite knowledge."); *Top RX Pharmacy*; Decision and Order, 78 FR 26069, 62341 (DEA Oct. 12, 2012) (same); *cf. Jones Total Health Care Pharmacy LLC and SND Health Care LLC v. Drug Enforcement Administration*, 881 F.3d 82 (11th Cir. 2018) (revoking pharmacy registration for, *inter alia*, dispensing prescriptions that prescriptions presented various red flags, i.e., indicia that the prescriptions were not issued for a legitimate medical purpose without resolving red flags).

red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions suggestive of potential diversion.

95. Fourth, as described below, Defendants also had duties under applicable state laws.

96. Recognizing a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970. The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals. Congress specifically designed the closed chain of distribution to prevent the diversion of controlled substances into the illicit market. Congress was concerned with the diversion of drugs out of legitimate channels of distribution and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market." Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain. All registrants—which should include all distributors of controlled substances and pharmacies dispensing controlled substances—must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion. When the supply chain participants at any level fail to fulfill their obligations, the necessary checks and balances collapse. The result is the scourge of addiction that has occurred.

97. The CSA requires distributors and pharmacies, along with other participants in the supply chain of controlled substances like opioids to: (a) limit sales within a quota set by the DEA for the overall production of controlled substances like opioids; (b) register to distribute opioids; (c) maintain effective controls against diversion of the controlled substances that they manufacture or distribute; and (d) identify suspicious orders of controlled substances and halt such sales.

98. To ensure that even drugs produced within quota are not diverted, federal regulations issued under the CSA mandate that all registrants "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). Registrants are not entitled to be passive (but profitable) observers, but rather "shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant." *Id.* Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. *Id.* Other red flags may include, for example, "[o]rdering the same controlled substance from multiple distributors."

99. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry. For this reason, identification of suspicious orders serves also to identify excessive volume of the controlled substance being shipped to a particular region.

100. The DEA has testified in this MDL that:

a. DEA registrants are required to block all suspicious orders of prescription opioids.[12]

b. Shipping a suspicious order is a per se violation of federal law.[13]

[12] *See* Prevoznik Dep. Vol II, 770:6 to 771:20, April 18, 2019 (DEA 30(b)(6) designee).
[13] *Id.* at 632:7 to 633:2.

c. If a wholesale distributor blocks a suspicious order, they should terminate all future sales to that same customer until they can rule out that diversion is occurring.[14]

d. After the fact reporting of suspicious orders has never been in compliance with federal law.[15]

101. Of course, due diligence efforts must be thorough: "the investigation must dispel all red flags indicative that a customer is engaged in diversion to render the order non-suspicious and exempt it from the requirement that the distributor 'inform' the [DEA} about the order. Put another way, if, even after investigating the order, there is any remaining basis to suspect that a customer is engaged in diversion, the order must be deemed suspicious and the Agency must be informed."[16] Indeed, the DEA may revoke a distributor's certificate of registration as a vendor of controlled substances if the distributor identifies orders as suspicious and then ships them "without performing adequate due diligence."[17]

102. To comply with the law, wholesale distributors, including Defendants, must know their customers and the communities they serve. Each distributor must "perform due diligence on its customers" on an "ongoing [basis] throughout the course of a distributor's relationship with its customer." *Masters Pharms., Inc.*, 80 Fed. Reg. 55,418, 55,477 (DEA Sept. 15, 2015), *petition for review denied*, 861 F.3d 206 (D.C. Cir. 2017).

---

[14] *Id.* at 628:24 to 629:15.
[15] *Id.* at 673:7 to 674:13 , 679:20 to 680:8.
[16] *Masters Pharmaceuticals, Inc.*, Decision and Order, 80 Fed. Reg. 55418-01 at *55477 (DEA Sept. 15, 2015).
[17] *Masters Pharmaceuticals*, 861 F.3d at 212. The *Decision and Order* was a final order entered by the DEA revoking Masters Pharmaceutical's certificate of registration, without which Masters Pharmaceutical could not sell controlled substances. In *Masters Pharmaceutical*, the D.C. Circuit Court of Appeals denied a petition for review, leaving intact the DEA's analysis and conclusion in the *Decision and Order*.

103. Pharmacy order data provides detailed insight into the volume, frequency, dose, and type of controlled and non-controlled substances a pharmacy typically orders. This includes non-controlled substances and Schedule IV controlled substances (such as benzodiazepines), which are not reported to the DEA, but whose use with opioids can be a red flag of diversion.

104. In addition to their duties as distributors, Defendants also had a duty to design and implement systems to prevent diversion of controlled substances in their retail pharmacy operations. Defendants had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

105. As acknowledged in an article CVS published in the New England Journal of Medicine, "[p]harmacies have a role to play in the oversight of prescriptions for controlled substances, and opioid analgesics in particular." Mitch Betses, R.Ph., and Troyen Brennan, M.D., M.P.H., *Abusive Prescribing of Controlled Substances - A Pharmacy View*, N. ENGL. J. MED. 369;11, Sept. 12., 2013, at 989-991. The DEA has identified "both pharmaceutical distributors and chain pharmacies as part of the problem" contributing to opioid abuse and related deaths. *Id.*

106. The National Retail Pharmacies have a particular "advantage" in meeting their obligations under the CSA because these entities can use "aggregated information on all prescriptions filled at the chain" in order to examine "patterns" of opioids and other "high-risk drugs" and target "inappropriate prescribing." *Id*. at 990. For example, a chain pharmacy should properly use its chainwide dispensing data to identify "high risk prescribers" by "benchmarking" prescription data based on "several parameters," including "volume of prescriptions for high-risk drugs," "the proportion of the prescriber's prescriptions that were for such [high-risk] drugs, as compared with the volume and proportion for others in the same specialty and region," cash

payment, ages of patients, and the prescriber's ratio of "prescriptions for noncontrolled substances with prescriptions for controlled substances." *Id*. This "[a]nalysis of aggregated data" from chain pharmacies can "target patterns of abuse," in the face of "the growing use of controlled substances and resulting illnesses and deaths." *Id.* Accordingly, as CVS touts, "innovative use of transparent data is only prudent." *Id.*

107. As CVS counseled, Defendants may not ignore red flags of illegal conduct and must use the information available to them to identify, report, and not fill prescriptions that seem indicative of diversion. That would include reviewing their own data, relying on their observations of prescribers, pharmacies, and customers, and following up on reports or concerns of potential diversion.

108. All suspicious conduct must be reported to relevant enforcement authorities. Further, Defendants must not fill or ship any suspicious prescription or order unless they have conducted an adequate investigation and determined that the prescription or order is not likely to be diverted into illegal channels.[18] Reasonably prudent distributors would not fall below this standard of care, and their failure to exercise appropriate controls foreseeably harms the public health and welfare.

109. In addition to their duties as a distributors, Defendants also had a duty to design and implement systems to prevent diversion of controlled substances and to monitor and report suspicious activity in their retail pharmacy operations. Specifically, Defendants had a duty to analyze data and store-level information for known red flags such as (a) multiple prescriptions to the same patient using the same doctor; (b) multiple prescriptions by the same patient using

[18] *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007) (applying federal requirements no less stringent than those of Ohio); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (D.C. Cir. 2017) (same).

different doctors; (c) prescriptions of unusual size and frequency for the same patient; (d) orders from out-of-state patients or prescribers; (e) an unusual or disproportionate number of prescriptions paid for in cash; (f) prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription "cocktails"; (g) volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose.

110. According to law and industry standards, if a pharmacy finds evidence of prescription diversion, the Board of Pharmacy and DEA must be contacted.

111. As distributors and as pharmacies, Defendants have a duty, and are expected, to be vigilant in ensuring that controlled substances are delivered only for lawful purposes.

112. State and federal statutes and regulations reflect a standard of conduct and care below which reasonably prudent distributors and pharmacies would not fall. Together, these laws and industry guidelines make clear that Defendants possess and are expected to possess, specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription opioids and of the risks and dangers of the diversion of prescription opioids when the supply chain is not properly controlled.

113. Further, these laws and industry guidelines make clear that Defendants have a responsibility to exercise their specialized and sophisticated knowledge, information, skill, and understanding to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

114. Reasonably prudent distributors and pharmacies would not fall below this standard of care, and their failure to exercise appropriate controls foreseeably harms the public health and welfare.

3. Defendants Were Aware of and Have Acknowledged Their Obligations to Prevent Diversion and to Report and Take Steps to Halt Suspicious Orders.

115. The regulations aim to create a "closed" system in order to control the supply and reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. Both because distributors handle such large volumes of controlled substances, and because they are uniquely positioned, based on their knowledge of their customers and orders, as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, distributors' obligation to maintain effective controls to prevent diversion of controlled substances is critical. Should a distributor deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses.

116. Defendants were well aware they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

117. Indeed, the DEA has repeatedly informed Defendants about their legal obligations, including obligations that were so obvious that they simply should not have required additional clarification. As former DEA agent Joseph Rannazzisi recently explained during a deposition in this MDL:

> Q. Someone says "Don't steal," do you have to put in there "from a supermarket"?
>
> A. No.
>
> Q. Someone says "Don't trespass on the property," do you have to put "wearing tennis shoes"?
>
> A. No.

> Q. Next, you got asked: "Well, you never instructed the companies to keep their files." Do you remember that?
>
> A. Yes, sir.
>
> Q. Would old files be important in monitoring -- in your ongoing monitoring? Would it be important that a company keep their files so that they can look back at them?
>
> A: Absolutely. That's the -- the whole idea behind maintaining a due diligence file is you have a history of purchases. That way you could see what they're doing and where they're going with their purchases.[19]

118. For example, it is not an effective control against diversion to identify a suspicious order, ship it, and wait as long as weeks to report it to law enforcement, potentially allowing those pills to be diverted and abused in the meantime.

119. During a 30(b)(6) deposition in this MDL, the DEA's Unit Chief of Liaison was asked whether the DEA made it "clear to industry that the failure to prevent diversion was a threat to public safety and the public interest." In response, he testified:

> Yes, I think it's established in 823 [the Controlled Substances Act] where it's part of our -- part of the registrant that is applying to be a registrant understands that they have to maintain effective controls . . . . they also know that these drugs themselves are scheduled controlled substances for a particular reason, because they're addictive, psychologically and physically they're addictive, so they know that these drugs have these properties within themselves. **So they would understand that these drugs are categorized or scheduled in that manner because they have the potential to hurt**.[20]

120. And Defendants did understand. As described below, at least Walgreens has itself acknowledged (internally) its understanding of the potential consequences of its failure to report and cease shipping suspicious orders.

---

[19] Rannazzisi Dep. at 646:20-647:19.
[20] Prevoznik Dep. Vol III at 942:3-8; 942:11-943:3 (emphasis added).

121. In fact, trade organizations in which Defendants have actively participated have acknowledged that distributors have been responsible for reporting suspicious orders for more than 40 years. The National Association of Chain Drug Stores ("NACDS") is a national trade association that represents traditional drug stores, supermarkets, and mass merchants with pharmacies—from regional chains with four stores to national companies. Its members and/or affiliate members also include stakeholders such as manufacturers, other distributors and other trade organizations as well. Most of the Defendants serve on the Board of Directors of NACDS. Chain Pharmacies have repeatedly chaired NACDS's Board of Directors, which determines the "strategic plan and positions" of the organization. During the last 12 years, representatives of CVS, Rite Aid, and Walgreens have always held Board of Directors or officer seats. Giant Eagle was also a member of the NACDS.

122. The Healthcare Distribution Management Association ("HDMA," now known as the Healthcare Distribution Alliance ("HDA"), and prior to 2000, known as the National Wholesale Druggists' Association ("NWDA")), is a national trade association representing distributors that has partnered with NACDS. The two groups viewed their relationship as a strategic "alliance." CVS also has been a member of the HDA.

123. In 2006, the NACDS issued a "Model Compliance Manual" intended to "assist NACDS members" in developing their own compliance programs. The Model Compliance Manual notes that a retail pharmacy may:

> "[G]enerate and review reports for its own purposes" and refers to the assessment tools identified by CMS in its Prescription Drug Benefit Manual chapter on fraud, waste and abuse, including:
>
> - Drug Utilization Reports, which identify the number of prescriptions filled for a particular customer and, in particular, numbers for suspect classes of drugs such as narcotics to identify possible therapeutic abuse or illegal activity by a customer. A customer with an abnormal number of prescriptions or prescription patterns for certain drugs should be identified

in reports, and the customer and his or her prescribing providers can be contacted and explanations for use can be received.

- Prescribing Patterns by Physician Reports, which identify the number of prescriptions written by a particular provider and focus on a class or particular type of drug such as narcotics. These reports can be generated to identify possible prescriber or other fraud.

- Geographic Zip Reports, which identify possible "doctor shopping" schemes or "script mills" by comparing the geographic location (zip code) of the patient to the location of the provider who wrote the prescription and should include the location of the dispensing pharmacy.

124. In 2007 and 2008, the HDA, began developing "Industry Compliance Guidelines" ("ICG") that aimed to outline certain "best practices" for distributors of controlled substances. As part of its development of the ICG, the HDA met with the DEA on at least three occasions. The HDMA also sought extensive input from its membership, as well as other groups such as the Pain Care Forum (mentioned *infra*). Internal discussions concerning the ICG further demonstrate the industry's knowledge of what was expected of them. For example, when deciding whether or not the guidelines should permit a distributor to still ship a part of an order identified as suspicious, the HDMA noted that one potential downside of this approach was that "DEA correspondence/interpretation do not support this practice."

125. The HDA released the ICG in 2008 and, in doing so, it emphasized that distributors were "[a]t the center of a sophisticated supply chain" and "uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers."[21]

[21] Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B at 1).

126. More recently, in in the appeal that arose from DEA's enforcement action against wholesaler Masters Pharmaceuticals, Inc. for its distribution of opioids, the HDA and NACDS submitted a joint amicus brief regarding the legal duty of distributors that acknowledged that "HDMA and NACDS members" had a duty to prevent diversion. *See Masters Pharmaceuticals, Inc. v. U.S. Drug Enforcement Admin.*, 2016 WL 1321983 (D.C. Cir. April 4, 2016). As described below, both the HDA and NACDS have both long taken the position that distributors have responsibilities to "prevent diversion of controlled prescription drugs" not only because they have statutory and regulatory obligations do so, but "as responsible members of society."

127. The requirement to report suspicious orders at the time (not after the fact) has always been clear and Defendants themselves have acknowledged as much through their various trade groups and associations. As described above, correspondence between the NWDA and the DEA, as early as 1984, illustrates that the DEA provided clear guidance well before the opioid crisis was unleashed. For example, in one letter to the NWDA, DEA Section Chief Thomas Gitchel emphasized that "the submission of a monthly printout of after-the-fact sales will not relieve a registrant from the responsibility of reporting excessive or suspicious orders," noting "**DEA has interpreted 'orders' to mean prior to shipment.**" Consistent with that understanding, the NWDA's 1984 Guidelines repeated the same directive.

128. In addition, the DEA, for example, in April 1987, sponsored a three-day "Controlled Substances Manufacturers and Wholesalers Seminar" that was attended by "over fifty security and regulatory compliance professionals representing forty-three major pharmaceutical manufacturers and wholesalers."[22] According to the executive summary of the event, Ronald Buzzeo held a session on "excessive order monitoring programs," wherein he explained:

[22] US-DEA-00025657.

> [A]ny system must be capable of both detecting individual orders which are suspicious, or orders which become suspicious over time due to frequency, quantity, or pattern. The NWDA system, for example, provides an excellent lookback, or trend system, but the ability to identify one time suspicious orders should not be overlooked as an element of the program." Another area at issue was whether DEA would take action against a registrant which reported an order and then shipped it. DEA pointed out that the company is still responsible under their registrations for acting in the public interest. Reporting the order does not in any way relieve the firm from the responsibility for the shipment.

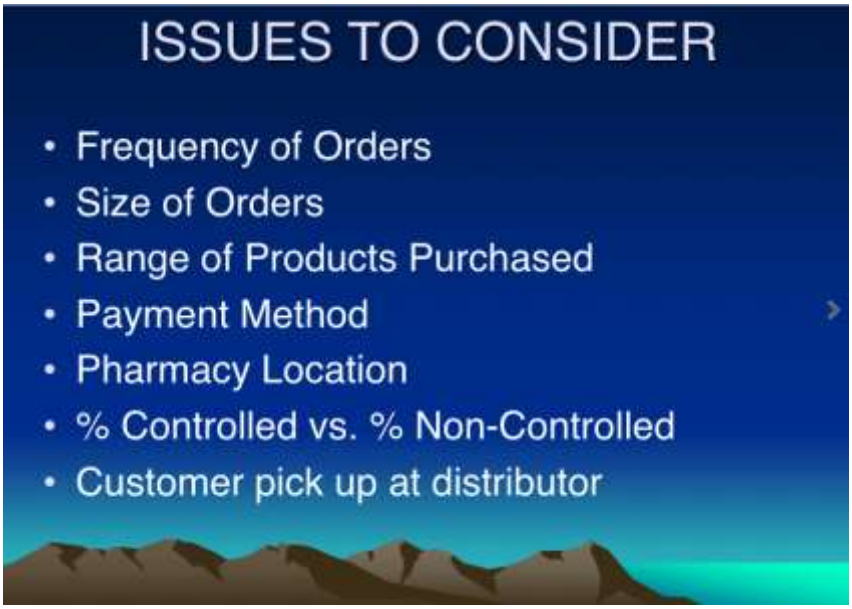
129. The DEA also repeatedly reminded Defendants of their obligations to report and decline to fill suspicious orders. Responding to the proliferation of internet pharmacies that arranged illicit sales of enormous volumes of opioids, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations.

130. Specifically, in August 2005, the DEA's Office of Diversion Control launched the "Distributor Initiative." The Distributor Initiative did not impose any new duties on distributors, but simply reminded them of their duties under existing law. The stated purpose of the program was to "[e]ducate and inform distributors/manufacturers of their due diligence responsibilities under the CSA by discussing their Suspicious Order Monitoring System, reviewing their [Automation of Reports and Consolidated Orders System ("ARCOS")] data for sales and purchases of Schedules II and III controlled substances, and discussing national trends involving the abuse of prescription controlled substances."[23] The CSA requires that distributors (and manufacturers) report all transactions involving controlled substances to the United States Attorney General. This data is captured in ARCOS, the "automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture

[23] Thomas W. Prevoznik, Office of Diversion Control, Distributor Initiative presentation (Oct. 22, 2013), https://www.deadiversion.usdoj.gov/mtgs/distributor/conf_2013/prevoznik.pdf.

through commercial distribution channels to point of sale or distribution at the dispensing/retail level—hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions,"[24] described above, from which certain data was recently made public.

131. As part of the Distributor Initiative, the DEA gave several presentations to distributors both individually and through presentations and discussions at Defendants' trade groups meetings directly targeted at some of the red flags of diversion that the Defendants were obligated to consider and monitor as part of their requirements under the law.



132. The DEA has hosted many different conferences throughout the years, including Pharmacy Diversion Awareness Conferences, to provide registrants with updated information about diversion trends and their regulatory obligations. The DEA also frequently presented at various other conferences for registrants at the national, state, or local level.

[24] U.S. Dept. of Justice, Drug Diversion Administration, Diversion Control Division website, https://www.deadiversion.usdoj.gov/arcos/index.html.

133. Through presentations at industry conferences and on its website, the DEA provided detailed guidance to distributors on what to look for in assessing their customers' trustworthiness. As an example, the DEA published "Suggested Questions a Distributor Should Ask Prior to Shipping Controlled Substances"[25]

134. In addition, the DEA sent a series of letters, beginning on September 27, 2006, to every commercial entity registered to distribute controlled substances, including chain pharmacy distributors. The 2006 letter emphasized that distributors are:

> one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.[26]

135. The letter also warned that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[27]

136. The DEA sent a second letter to distributors on December 27, 2007. Again, the letter instructed that, as registered distributors of controlled substances, they must each abide by statutory and regulatory duties to "maintain effective controls against diversion" and "design and

---

[25] U.S. Dept. of Justice DEA, Diversion Control Division website, Pharmaceutical Industry Conference (Oct 14 & 15, 2009), *Suggested Questions a Distributor should ask prior to shipping controlled substances*, Drug Enforcement Administration *available at* https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf; Richard Widup, Jr., Kathleen H. Dooley, Esq., *Pharmaceutical Production Diversion: Beyond the PDMA*, Purdue Pharma and McGuireWoods LLC, *available at* https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf.

[26] Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Off. of Diversion Control, Drug Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006), filed in *Cardinal Health, Inc. Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51 ("2006 Rannazzisi Letter").

[27] *Id.*

operate a system to disclose to the registrant suspicious orders of controlled substances."[28] DEA's letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (*e.g.*, by specifically identifying an order as suspicious, not merely transmitting ARCOS data to the DEA).

137. In September 2007, the NACDS on behalf of its members, the Defendants, among others, also attended a DEA conference at which the DEA reminded registrants that not only were they required to report suspicious orders, but also to halt shipments of suspicious orders. Walgreens, specifically, registered for the conference.

138. The DEA's regulatory actions against the three largest wholesale distributors further underscore the fact that distributors such as Defendants were well aware of their legal obligations. There is a long history of enforcement actions against registrants for their compliance failures. For example, in 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against three of Cardinal Health's distribution centers and on December 23, 2016, Cardinal Health agreed to pay the United States $44 million to resolve allegations that it violated the CSA in Maryland, Florida, and New York. Similarly, on May 2, 2008, McKesson entered into an Administrative Memorandum of Agreement ("AMA") with the DEA related to its failures in maintaining an adequate compliance program. Subsequently, in January 2017, McKesson entered into an Administrative Memorandum Agreement ("AMA") with the DEA wherein it agreed to pay a $150 million civil penalty for, *inter alia*, failure to identify and report suspicious orders at several of its facilities.

[28] Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in Cardinal Health, Inc. v. Holder, No. 1:12-cv00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8 ("2007 Rannazzisi Letter");*see also* CVS-MDLT1000091513; WAGMDL00757797.

139. The DEA has also repeatedly affirmed the obligations of pharmacies to maintain effective controls against diversion in regulatory action after regulatory action.[29] The DEA, among others, also has provided extensive guidance to pharmacies on how to identify suspicious orders and other evidence of diversion.

140. DEA has repeatedly emphasized that retail pharmacies, such as Defendants, are required to implement systems that detect and prevent diversion and must monitor for and report red flags of diversion. When red flags appear, the pharmacy's "corresponding responsibility" under 21 C.F.R. § 1306.04(a) requires it either to take steps (and document those steps) to resolve the issues or else to refuse to fill prescriptions with unresolvable red flags.[30]

141. DEA has identified several types of "unresolvable red flags" which, when present in prescriptions presented to a pharmacist, may never be filled by the overseeing pharmacist. These unresolvable red flags include: a prescription issued by a practitioner lacking valid licensure or registration to prescribe the controlled substances; multiple prescriptions presented by the same practitioner to patients from the same address, prescribing the same controlled substances in each presented prescription; a high volume of patients presenting prescriptions and paying with cash; and, a prescription presented to by a customer who has traveled significant and unreasonable distances from their home to see a doctor and/or to fill the prescription at the pharmacy.

---

[29] *See, e.g.*, Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195; 77 Fed. Reg. 62,316 (DEA Oct. 12, 2012) (decision and order); East Main Street Pharmacy, 75 Fed. Reg. 66,149 (DEAOct. 27, 2010) (affirmance of suspension order); Holiday CVS, L.L.C. v. Holder, 839 F.Supp.2d 145 (D.D.C. 2012); Townwood Pharmacy; 63 Fed. Reg. 8,477 (DEA Feb. 19, 1998) (revocation of registration); Grider Drug 1 & Grider Drug 2; 77 Fed. Reg. 44,069 (DEA July 26, 2012) (decision and order); The Medicine Dropper; 76 Fed. Reg. 20,039 (DEA April 11, 2011) (revocation of registration); Medicine Shoppe-Jonesborough; 73 Fed. Reg. 363 (DEA Jan. 2, 2008) (revocation of registration).

[30] *Pharmacy Doctors Enterprises, Inc. v. Drug Enf't Admin.*, No. 18-11168, 2019 WL 4565481, at *5 (11th Cir. Sept. 20, 2019).

142. DEA guidance also instructs pharmacies to monitor for red flags that include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances as compared to other practitioners in the area, and (2) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time. Most of the time, these attributes are not difficult to detect and should be easily recognizable by Defendants' diversion control systems.

143. The DEA has also explained these red flags in individual meetings with Defendants. For example, in December 2010, DEA hosted a meeting with CVS's representatives and counsel and advised CVS of the "red flags . . . that a pharmacy should be familiar with in order to carry out its corresponding responsibility to ensure that the controlled substances are dispensed for a legitimate medical purpose."[31]

144. Examples of red flags that the DEA identified during its meeting with CVS include:

a. many customers receiving the same combination of prescriptions (*i.e.*, oxycodone and alprazolam);

b. many customers receiving the same strength of controlled substances (*i.e.*, 30 milligrams of oxycodone with 15 milligrams of oxycodone and 2 milligrams of alprazolam);

c. many customers paying cash for their prescriptions;

d. many customers with the same diagnosis codes written on their prescriptions (*i.e.*, back pain, lower lumbar, neck pain, or knee pain); and

e. individuals driving long distances to visit physicians and/or to fill prescriptions.[32]

[31] Declaration of Joe Rannazzisi in *Holiday CVS, L.L.C. v. Holder*, 839 F. Supp.2d 145 (D.D.C. 2012).
[32] *Id.*

145. Similarly, in 2011, the DEA took Walgreens "to the woodshed" over its dispensing cocktail drugs and opioids to questionable out of state customers, customers with the duplicate diagnoses, young people, and customers only paying cash. Many of these same red flags were highlighted in the 2009 Walgreens Order to Show Cause and resulting 2011 Memorandum of Agreement ("MOA").

146. A more fulsome discussion of the various settlement agreements and enforcement actions against CVS, Walgreens, Rite Aid and Walmart is below.

147. As another example, in a 2016 presentation to the American Pharmacists Association, the DEA reiterated that retail pharmacies must watch for red flags such as: large numbers of customers who: receive the same combination of prescriptions, receive the same strength of controlled substance prescription (often for the strongest dose), have prescriptions from the same prescriber, and have the same diagnosis code.

148. Many of these red flags are acknowledged in a "Stakeholders" memorandum created by many of the Chain Pharmacies, including CVS, Rite Aid, and Walgreens, others in the business of selling controlled substances for profit, like Purdue Pharma and Cardinal Health, and their trade organizations, including the HDMA and the NACDS.

4. Defendants Were Uniquely Positioned to Guard Against Diversion.

149. Not only do Chain Pharmacies often have firsthand knowledge of dispensing red flags – such as distant geographic location of doctors from the pharmacy or customer, lines of seemingly healthy patients, cash transactions, and other significant information – but they also have the ability to analyze data relating to drug utilization and prescribing patterns across multiple retail stores. As with other distributors, these data points give the Chain Pharmacies insight into prescribing and dispensing conduct that enables them to prevent diversion and fulfil their obligations under the CSA.

150. Indeed, CVS Health president and CEO Larry Merlo has described the company as "America's front door to health care with a presence in nearly 10,000 communities across the country," which allowed it to "see firsthand the impact of the alarming and rapidly growing epidemic of opioid addiction and misuse."[33]

151. As explained above, in addition to their duties as distributors, the Chain Pharmacies also had a duty to design and implement systems to prevent diversion of controlled substances in their retail pharmacy operations. Specifically, the Chain Pharmacies had a duty to analyze data and the personal observations of their employees for known red flags such as (a) multiple prescriptions to the same patient using the same doctor; (b) multiple prescriptions by the same patient using different doctors; (c) prescriptions of unusual size and frequency for the same patient; (d) orders from out-of-state or distant patients or prescribers; (e) an unusual or disproportionate number of prescriptions paid for in cash; (f) prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription "cocktails"; (g) volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose. The Chain Pharmacies had the ability, and the obligation, to look for these red flags on a patient, prescriber, store, and chain level, and to refuse to fill and to report prescriptions that suggested potential diversion.

152. As described above and further below, the Chain Pharmacies also possessed sufficiently detailed and valuable information that other companies were willing to pay them for it. In 2010, for example, Walgreen's fiscal year 2010 SEC Form 10-K disclosed that it recognizes

[33] *See, e.g.*, David Salazar, *CVS Health Unveils New PBM, Pharmacy Efforts to Curb Opioid Abuse*, (Sept. 21, 2017), https://drugstorenews.com/pharmacy/cvs-health-unveils-new-pbm-pharmacy-efforts-curb-opioid-abuse

"purchased prescription files" as "intangible assets" valued at $749,000,000.[34] In addition, Walgreens's own advertising has acknowledged that Walgreens has centralized data such that customers' "complete prescription records" from Walgreens's "thousands of locations nationwide" are *"instantly available."*

153. Similarly, CVS's Director of Managed Care Operations, Scott Tierney, testified that CVS's data vendors included IMS Health, Verispan, and Walters Kluwers and that CVS used the vendors for "analysis and aggregation of data" and "some consulting services." He also testified that CVS would provide the vendors with "prescriber level data, drug level data, plan level data, [and] de-identified patient data."[35]

154. Each of the Chain Pharmacies had complete access to all prescription opioid dispensing data related to its pharmacies in the County, complete access to information revealing the doctors who prescribed the opioids dispensed in its pharmacies in and around the County, and complete access to information revealing the customers who filled or sought to fill prescriptions for opioids in its pharmacies in and around the County. Each of the Chain Pharmacies likewise had complete access to information revealing the customers who filled or sought to fill prescriptions for opioids in its pharmacies in and around the County, complete access to information revealing the opioids prescriptions dispensed by its pharmacies in and around the County, and complete access to information revealing the opioids prescriptions dispensed by its pharmacies in and around the County. Further, each of the Chain Pharmacies had complete access to information revealing the geographic location of out-of-state doctors whose prescriptions for opioids were being filled by its pharmacies in and around the County and complete access to

[34] https://www.sec.gov/Archives/edgar/data/104207/000010420710000098/exhibit_13.htm
[35] Joint Appendix in *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 687134 (U.S.) *245-46 (Feb. 22, 2011).

information revealing the size and frequency of prescriptions written by specific doctors across its pharmacies in and around the County.

155. Defendants, until March 2020, resisted producing their dispensing data in this MDL, and now seek to claw it back. Thus, while Defendants had access to data that would have demonstrated their knowledge of red flags and potential diversion, plaintiffs have not been able to access that data to fully analyze both what Defendants knew, or should have known, and the impact that they could have had in preventing diversion in the County.

5. Defendants Failed to Maintain Effective Controls Against Diversion.

156. As described further below, the Chain Pharmacies failed to fulfill their legal duties and instead, routinely distributed and/or dispensed controlled substances while ignoring red flags of diversion and abuse. The unlawful conduct by these Defendants is a substantial cause for the volume of prescription opioids and the public nuisance plaguing the County.

i. CVS

a. CVS Failed to Maintain An Effective Suspicious Order Monitoring System or to Complete Necessary Due Diligence.

1. CVS Lacked A Genuine Suspicious Order Monitoring System for Much of the Relevant Time.

157. CVS distribution centers, in tandem with outside wholesalers, such as Cardinal, supplied opioids to CVS pharmacy stores until October 2014. CVS self-distributed hydrocodone and hydrocodone combination products to its own stores, of which CVS had approximately 6,000 by 2006 and 9,700 by 2014. Hydrocodone (HCP) was previously a Schedule 2 opioid, but rescheduled to FDA Schedule 2 status October 6, 2014. CVS ceased self-distributing hydrocodone the same day the rescheduling took effect.

158. CVS pharmacies nationwide placed orders with CVS distribution centers through CVS's central mainframe computer ordering system.

159. Before 2009, CVS, which stocked and sold opioids at more than 9,000 stores across the country, lacked any meaningful suspicious order monitoring ("SOM"). Instead, CVS relied on the gut instincts of pickers and packers of the drugs in the distribution center – workers responsible for pulling items off distribution shelves for delivery to pharmacy stores -- to identify "really big" orders that they believed were simply too large. This, of course, was not an effective SOM system.

160. Moreover, CVS lacked a training program to train its Pickers and Packers how to identify unusual orders of size, frequency, or pattern. CVS also did not have any written policies, procedures, or protocols with respect to the Pickers' and Packers' obligations until August, 2013. And, there were no formal job requirements to be employed as a Picker and Packer.

161. In 2007, with the help of an outside consultant, CVS began work on a Standard Operating Procedure Manual ("SOP") that was intended to cover all facets of DEA controlled substances compliance, including suspicious order monitoring. However, by the Summer of 2010, neither the final manual nor the SOM section was complete: Internal documents from that time acknowledge that CVS was "still in the process of writing the suspicious order monitoring section of this standard operating procedure." In fact, the section of the Standard Operating procedures for Suspicious Order Monitoring states "**BEING DEVELOPED AND WRITTEN."**

162. Drafts of the SOP Manual, meanwhile, show CVS understood, or should have understood, that this was unacceptable. The draft manual provides that: "CVS is responsible for ensuring compliance with DEA regulatory requirements, and that responsibility cannot be abdicated or transferred to anyone else." Despite this acknowledgement, when the first version of the SOP Manual was issued in December 2007 and for multiple revisions thereafter, the SOM section still remained incomplete. It was not completed until August of 2010. Completion of the Manual in 2010 did not equate to compliance, however.

163. As John Mortelliti, CVS's Director of Loss Prevention, wrote in November 2009, this had become "a big issue with CVS and the DEA," and he was "trying to get a rough draft SOM SOP" before a DEA meeting. CVS only incorporated the final missing SOMS section because of the need to fulfill an apparent promise to provide it to the DEA.

164. CVS Indiana was audited and investigated by the DEA for its distribution practices on August 24, 2010. The day after the DEA's audit of CVS's distribution practices began, on August 25, 2010, CVS Pharmacy, Inc. sent a new Standard Operating Procedure, which included for the very first time a policy on SOM. CVS Pharmacy, Inc. internally posted the SOP be posted at 1:35 pm on August 26, 2010. The document was hastily put together. The SOM section was actually cut and pasted into the SOP twice.

165. On September 1, 2010, John Mortelliti sent an e-mail to Terrance Dugger who was present during the DEA audit. The subject of the e-mail and the attachment is "DEA Speaking Points", the importance was listed as high. He writes: "Terrence, This is for the DEA. The corrections listed below have been updated. It is ok to review this with the agents."

166. Mr. Mortelitti then sent the same presentation on the same day to another group of CVS employees writing: "These are the final approved speaking points for the DEA agents if they come to one of your facilities and question suspicious monitoring. It is ok to share this document. Please be sure your team understands it before presenting so it **doesn't look like a prop instead of a tool."** The presentation sent by Mr. Mortelitti to be shared with the DEA was not correct and was not the procedure being used by CVS.

167. CVS had a "CVS DEA compliance coordinator" in name only. A CVS employee who held the position from 2008 to 2014 said that her title was only "for reference in SOPs," and not her real job. For "personnel purposes," she was never considered the CVS DEA compliance

coordinator. Moreover, she had nothing to do with suspicious order monitoring, other than "updating the SOP with what was provided for the program."[36] This, according to CVS's "DEA Compliance Coordinator."

2. CVS Failed to Remedy Fatal Flaws in the System it Slowly Developed.

168. It was only in 2009 that CVS began using a computer algorithm that flagged potentially suspicious orders needing additional investigation. The automated program was delivered by an outside vendor to CVS in December of 2008.

169. CVS called the output of the flagged orders an Item Review Report ("IRR").

170. The SOM algorithm delivered in December 2008 was designed to "pend" (or identify) an order with a score of 0.15 or higher as potentially suspicious. The higher the score the more likely the order was potentially suspicious. In July, 2009 CVS reported to the algorithm designer that the SOM model was pending a large number of orders that CVS believed were "not suspicious on their face" and it requested that the model be changed. As a result, revised co-efficients for the algorithm were delivered to CVS on August 27, 2009 and the pend score of .15 remained the same. Between June, 2010 and August, 2010 Mortelliti adjusted the IRR pend score from .15 to .65. The higher the score, the less sensitive the model, flagging fewer potentially suspicious orders for investigation. On February 8, 2011 a completely retuned SOM algorithm with another set of co-efficients was again delivered to CVS by the algorithm designer. The February, 2011 changes returned the pend score to .15. CVS again changed the pend score to .65.

171. IRRs were the primary SOM process. A CVS corporate representative explained, on behalf of the company, "for the most part," if an order was not flagged as suspicious under the

[36] Deposition testimony of CVS employee Amy Propatier (Nov. 29, 2018) at 79:20-80:7; 80:21-81:2; 82:19-22; 138:21-140:1.

IRR system, there would be no due diligence of that order. Yet, CVS neglected to provide written instructions to its employees for how to perform that critical review until February 29, 2012.

172. CVS's IRR system was deficient and failed in many respects to meet CVS's obligations.as a distributor.

173. CVS also learned in 2010 that its SOM algorithm was not working properly because it monitored by drug, not active ingredient, meaning that changes in a drug's description or name caused historical data to be lost. Thus, the system was unable to determine that orders for these drugs exceeded or diverged from prior volumes or patterns.

174. CVS's SOMS algorithm also failed to consider outside vendors orders. In other words, CVS's SOM system would not track how many opioids CVS was ordering from third party distributors such as Cardinal when evaluating whether to distribute opioids to one of its pharmacies. CVS knew this was a problem, as a "[s]tore may order a little from both the OV [outside vendor] and DC [CVS distribution center] to stay under the radar." It also knew that excluding outside vendor data meant CVS "may ship a potentially reportable suspicious order from [its] DC." Stores, including one that had a "68,000 hydrocodone pill loss," could also place telephone orders to outside vendors, into which there was "no visibility . . . until a later time." This deficiency is particularly glaring because, at a corporate level, CVS had full access to the orders its pharmacies placed to outside vendors.

175. Acknowledging the ineffectiveness and deficiencies within its SOM system, CVS hired new consultants in 2012 to troubleshoot its existing SOM systems for the purpose of either fixing the deficient system or developing a new SOM system so as to attempt to become compliant with the law.

176. Still, as late as July 2013, internal e-mail reflects that CVS's primary tool for investigating suspicious orders relied on data that was months or even years old and made any analysis, "for the most part, irrelevant and pointless."

177. Not until mid to late 2014 did CVS fully implement anew SOM system. Even still, CVS encountered problems in evaluating suspicious orders for opioids and its SOMS was entirely lacking. More specifically, CVS implemented a new SOM system in the Indianapolis distribution system in March of 2014. The deployment was further delayed due to system data feed issues that created inaccuracies in the SOM historical data. A risk analysis of the new system was conducted in June of 2014. The risk level was determined to be high for the SOM system in the following categories covering seemingly every aspect of its operation: inconsistent due diligence in SOM analysts reaching out to stores to investigate suspicious orders; inconsistency in documenting due diligence investigations of suspicious orders; lack of engagement by the Management Team; lack of communication between the SOM Management Team and SOM Analysts; lack of resources to handle the rollout of the new SOM system to all distribution centers; lack of clarity in how the new SOM system is identifying suspicious orders. Essentially, the key components of a compliant and effective SOMS system. That same year, CVS stopped distributing opioids at the wholesale level

178. Meanwhile, on August 5, 2013 the DEA began another audit and investigation of the CVS distribution center in Indiana. CVS's own documents acknowledge that the DEA's investigation was focused on its failure to maintain a SOM program for controlled substances.

179. In response to queries from the DEA, CVS wrote a letter to the DEA revealing that it had only stopped seven suspicious orders across the entire country. Right before sending the letter the author, Mark Nicastro, head of the CVS distribution center in Indiana, conceded internally that "I wish I had more stopped orders that went back further." Sadly, while Mr. Nicastro

was writing the letter on CVS's behalf to the DEA, he couldn't even locate the SOP for the SOM writing to Pam Hinkle, "For the life of me I can't find the SOP for SOM. Can you send me an electronic copy please? I have been on the logistics website, looked through hundreds of e-mails, nothing. I'm surprised it is not on the website." Ms. Hinkle, Sr. Manager for Logistics, quality and Compliance for CVS, responds that she too is unsure of the final version of the SOP SOM. CVS sent the wrong version of the SOP SOM to the DEA.

180. In May of 2014, CVS had a closing meeting with the DEA related to the distribution center audit. According to handwritten notes from a CVS employee who attended the meeting, the "most serious" violation is "failure to design" a SOM system. An internal CVS e-mail summarizing the meeting made a similar statement: DEA determined that CVS "faile[d] to maintain an SOM program." The head of CVS's distribution center in Indiana described Betsy Ferguson's, CVS's in-house counsels', confrontation with the DEA during the meeting writing: "Dan [DEA Agent] finally pushed Betsy's button and the gloves came off. . . . Betsy made it very clear that a letter of admonishment was one thing. Anything other than that and she wanted an opportunity to do a presentation to his boss and her boss about what we do with SOM. Anything more than a letter and we would meet in D.C. in courts just like Walgreens did."

181. The DEA issued its closing letter concluding that CVS failed to design and maintain a system to detect suspicious and report suspicious orders for Schedule III-V Controlled Substances as required by Title 21 United States Code (USC) 821, Title 21 USC 823(e)(1), and Title 21 Code of Federal Regulations (CFR) 1301.74(b) in violation of Title 21 USC 842(a)(5).

3. CVS Failed to Perform Due Diligence.

182. All orders that appeared on the IRR required a thorough due diligence investigation, but only a very small percentage were subjected to appropriate due diligence. From early/mid-

2009 through early 2011, one employee, Mortelliti, the Director of Loss Prevention, "was taking the first pass through the IRR himself." According to CVS's corporate witness, "Mr. Mortelliti's practice would have been to review the report on a daily basis and determine whether items on the report warranted further review and due diligence and conduct review and due diligence as he deemed appropriate." At select times in 2013, CVS had only one full-time employee in the position of "SOM analyst" reviewing all potentially suspicious orders for every pharmacy in the country. The SOM system would identify orders as potentially suspicious based on a number of factors and "pend" the order. Even though the orders had been identified as potentially suspicious, the CVS SOM analysts would conduct an "in depth" dive on only select orders. In fact, the SOM program could identify as many as 1,000 suspicious orders a day; the CVS employee would only do a "deep dive" on one to six orders per day.

183. Even as late as 2012, CVS's SOMS was clearly little more than window dressing. For example, CVS's own SOMS policy specified that if multiple orders for the same store are flagged during the same month, all orders after the first order will ***not*** be investigated and will be ***automatically released*** based on the release of the first order.

5. If order is cleared on 1st of month and cleared, and store then orders again that month it won't be looked at
    a. If System flags it, we are required to look at it and document why it was released, currently we are simply releasing order based on past due diligence on a different order.

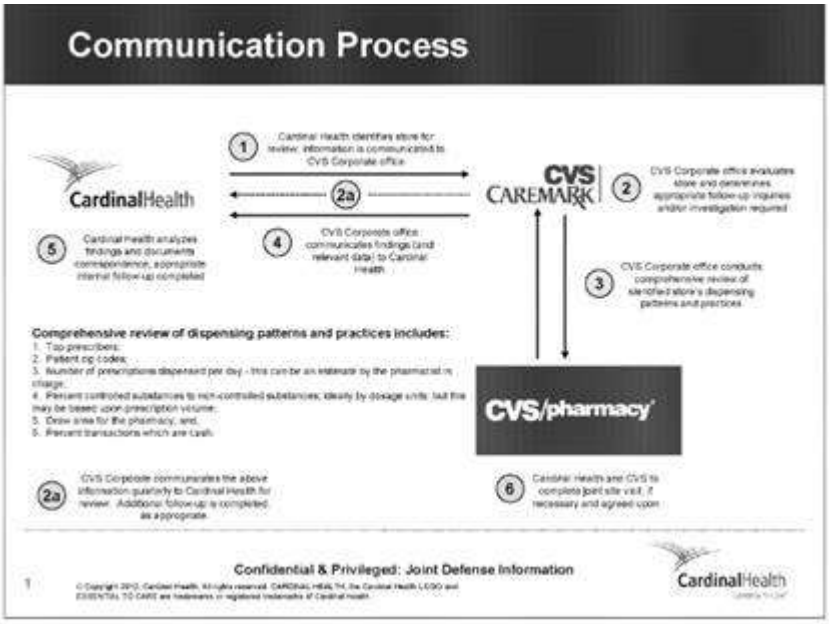
184. <u>As noted above, as of November 21, 2013, CVS had only reported seven suspicious orders to the DEA across all of its distribution centers and pharmacies in the United States</u>. The first suspicious order CVS ever reported was on February 29, 2012. ***<u>CVS reported no suspicious orders in Ohio.</u>***

b. CVS Conspired with Cardinal and McKesson to Prevent Suspicious Order Monitoring of Its Retail Pharmacies.

185. CVS's collaboration with Cardinal distributors went from lobbying to actually preventing adequate due diligence investigations of suspicious opioid orders. CVS knows that Cardinal and McKesson have independent due diligence obligations under the CSA to monitor all sales of controlled substances for orders which deviate in size, pattern or frequency. CVS understood that, to do so effectively, Cardinal and McKesson would require access to its dispensing information. CVS did not provide dispensing information to Cardinal or McKesson. In an email from Paul Farley to Michael Mone, both Cardinal employees, Farley wrote, "I spoke with Brian Whalen at CVS a couple of times this morning… They will not provide the doctor or patient information you requested unless it is requested by the DEA. He was quite adamant about this."[37] CVS prevented Cardinal and McKesson from obtaining access to critical dispensing information for its pharmacies to enable Cardinal and McKesson to conduct adequate due diligence of its pharmacies. Prior to 2013, Cardinal and McKesson did not investigate CVS by calling its pharmacists or visiting CVS stores as they did with other pharmacies. Instead, distributors were instructed to contact CVS's loss prevention offices at corporate headquarters to inquire about suspicious orders. ensuring that any investigation into CVS ordering of opioids was conducted by CVS alone.

186. As a result, CVS controlled all "due diligence investigations" of its opioid orders. This chart produced by Cardinal depicts the due diligence "investigations" of CVS orders:

[37] *See* Exhibit 4 to Deposition testimony of Donald Morse, Anti-Diversion of Controlled Substances at Cardinal (December 13, 2018), pp. 2-3.



187. CVS also prevented its distributors from independently determining the appropriate order thresholds for opioids at CVS stores. CVS contractually protected its right to establish and change its threshold requirement for Schedule II controlled substances with Cardinal. The agreement expressly states that CVS has the discretion under the contract to set its threshold quantities for controlled substances at any level CVS deems appropriate:

> CVS requires the ability to adjust (up or down) the quantity of product our stores receive, this adjustment will be made on an NDC by NDC basis and will include a Threshold Quantity and an Adjustment Percentage. **Both the Threshold Quantity and Adjustment Percentage can be set to any value CVS deems appropriate.**

c. CVS Acquired Omnicare Knowing of Systemic Failures to Control Against Diversion, But Instead of Reform, Continued Business As Usual.

188. In 2015, CVS Health Corp. acquired Omnicare, which provides pharmacy-related services to long-term care facilities and other health care facilities throughout the United States. Omnicare dispenses controlled substances under Certificates of Registration issued by the DEA.

From 2006 through 2014, Omnicare distributed ***2,487,060*** dosage units of oxycodone and hydrocodone into Lake County, Ohio.

189. When CVS acquired Omnicare, CVS was fully aware the DEA had previously investigated Omnicare for "alleged errors and deficiencies in paperwork requirements for controlled-substances dispensing at several of the company's pharmacies in Ohio."[38] Omnicare publicly acknowledged the DEA's Ohio investigation in its 2010 SEC filings, which Omnicare later settled in 2012. CVS was also aware the DEA had previously investigated Omnicare in 2007 for countrywide violations of the CSA that also led to a settlement with the Agency. In Ohio, the DEA determined that between 2007 and 2012 Omnicare:

- dispensed controlled substances to residents of long-term care facilities without valid prescriptions, including but not limited to dispensing controlled substances pursuant to written orders that did not contain all of the elements of a valid prescription including the signature of the prescribing practitioner, in violation of 21 U.S.C. §§ 353(b), 829 and 842(a)(1) and 21 C.F.R. §§ 1306.11 and 1306.21;

- failed to comply with all of the elements of the emergency oral prescription requirements set forth in 21 C.F.R. § 1306.11(d), including but not limited to dispensing Schedule II controlled substances or authorizing facility staff to remove Schedule II controlled substances from emergency supplies located at long-term care facilities without oral authorizations directly from prescribing practitioners and failing to notify the nearest office of DEA if the prescribing individual practitioner failed to deliver a written prescription to the pharmacy within seven days, in violations of 21 U.S.C §§ 8429(a)(1) and (a)(5);

- dispensed controlled substances to residents of long-term care facilities without prescriptions meeting the requirements of 21 C.F.R. §§ 1306.05(a) and 1306.11(f), including but not limited to dispensing controlled substances pursuant to pre-populated prescriptions prepared by the pharmacies and dispensing controlled substances pursuant to written orders that lacked one or more of the following: the signature of the practitioner, the date of issuance, the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, or the name, address and DEA registration number of the practitioner, in violation of 21 U.S.C § 842(a)(1);

[38] "Omnicare Faces Federal Probe, Wall Street Journal, 28 Oct. 2010.

- not maintaining records of prescriptions for controlled substances listed in Schedule II in compliance with 21 C.F.R. part 1304, in violation of 21 U.S.C. § 842(a)(5).[39]

190. In 2012, Omnicare paid $50 million to resolve these allegations.

191. Since its acquisition by CVS, Omnicare has continued to violate the CSA. This week Omnicare settled additional charges made by the DEA paying $15.3 million. The DEA recently found that Omnicare again violated the CSA:

> in its handling of emergency prescriptions, its controls over the emergency kits, and its processing of written prescriptions that had missing elements. The federal investigation found that Omnicare failed to control emergency kits by improperly permitting long-term care facilities to remove opioids and other controlled substances from emergency kits days before doctors provided a valid prescription. The investigation also revealed that Omnicare had repeated failures in its documentation and reporting of oral emergency prescriptions of Schedule II controlled substances.[40]

177. Many of the recent allegations made by the DEA repeat precisely those violations Omnicare engaged in before 2012. The Acting Administrator of the DEA stated, "Omnicare failed in its responsibility to ensure proper controls of medications used to treat some of the most vulnerable among us."[41] CVS, fully aware of the past compliance failures and fully aware of the enormous danger posed to the public from the diversion of opioids, failed to properly monitor and create a corporate system through which it could ensure that its subsidiaries complied with the CSA.

d. CVS Failed to Maintain Effective Controls Against Diversion in the County.

192. Through seven pharmacies in the County, CVS purchased more than ***16.9 million*** dosage units of oxycodone and hydrocodone from 2006 to 2014, the years for which ARCOS data

[39] Settlement Agreement between DEA and Omnicare dated May 10, 2012.
[40] Press Release May 13, 2020, "Omnicare, Inc. agrees to pay more than $15 million to resolve allegations it improperly dispensed narcotics at long term care facilities."
[41] *Id.*

is available. Of that, CVS distribution centers (CVS Indiana, CVS RX Services, CVS TN) distributed more than ***7.2 million*** dosage units of hydrocodone into Lake County from 2006-2014, and Lake County CVS stores ordered an additional 561,450 dosage units of hydrocodone from Cardinal during that same time-frame.

193. As a vertically integrated distributor and dispenser of prescription opioids, CVS knew or should have known that an excessive volume of pills was being sold into Ohio and Lake County and ultimately, onto its streets. CVS's activities as a distributor and a seller or dispenser of opioids are inextricably linked.

194. CVS violated the standard of care for a distributor by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities it knew or should have known could not be justified and signaled potential diversion.

195. The sheer volume of prescription opioids distributed to and dispensed by CVS pharmacies in and around the County, with a population of fewer than 210,000 residents during the same time period, is indicative of potential diversion and required appropriate due diligence.

196. Further, a Willoughby CVS alone bought over 4.5 million dosage units of oxycodone and hydrocodone from 2006-2014, which was enough for approximately 22 pills per year for each of the 22,259 people who live in the city of Willoughby—notwithstanding the fact that there was also a Walgreens located only a half a mile away that flooded the same area with over 3.8 million dosage units of oxycodone and hydrocodone from the same time period. On top of that, there were at least nine additional pharmacies within a five mile radius of these high-buying Walgreens and CVS locations.

197. CVS funneled far more opioids into Ohio and the County, and out of its pharmacy doors, than could have been expected to serve legitimate medical use, and ignored other red flags of diversion, including but not limited to suspicious orders.

198. It cannot be disputed that CVS, was aware of the suspicious orders that flowed from its distribution facilities into its own stores. CVS simply refused to identify, investigate, and report suspicious orders even though CVS knew, or should have been fully aware, that opioids it distributed and sold were likely to be diverted. Conversely, CVS failed to report suspicious orders, failed to meaningfully investigate or reject suspicious orders, and failed to prevent diversion, or otherwise control the supply of opioids flowing into Ohio the County.

199. Upon information and belief, CVS failed to analyze: (a) the number of opioid prescriptions filled by its pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; and (c) the number of opioid prescriptions filled relative to other drugs.

200. CVS was, or should have been, fully aware that the opioids being distributed and dispensed by it were likely to be diverted; yet, it did not take meaningful action to investigate or to ensure that it was complying with its duties and obligations with regard to controlled substances, including its responsibility to report suspicious orders and not to ship such orders unless and until due diligence allayed the suspicion.

201. Given CVS's retail pharmacy operations, in addition to its role as a wholesale distributor, CVS knew or reasonably should have known about the disproportionate flow of opioids into Ohio and the County and the operation of "pill mills" that generated opioid prescriptions that, by their quantity or nature, were red flags for, if not direct evidence of, illicit supply and diversion.

202. In addition, CVS knew, or deliberately turned a blind eye, to its pharmacies' role in diversion of dangerous drugs. At the pharmacy level, discovery will reveal that CVS knew or should have known that its pharmacies in Ohio, and the surrounding area, including West Virginia, Michigan, and Kentucky, were (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash; (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription "cocktails";[42] (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets. CVS had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

203. Failures regarding dispensing in CVS's Florida stores also allowed diverted opioids to be funneled into the County. The well-travelled path between Florida and Ohio is described further below. And, CVS saw huge increases in the quantity of oxycodone it dispensed in Florida from 2006 to 2010. For example, starting with an already high baseline, a single CVS ordered

[42] According to definitions applied by CVS for suspicious order monitoring purposes, "cocktails for opioids are methadone, muscle relaxants, stimulants and benzodiazepines."

approximately four times the amount of oxycodone a typical pharmacy orders in one year in 2006. By 2010, the same pharmacy's 10-month history showed quantities more than thirty times the amount of oxycodone a typical pharmacy orders in one year, and the pharmacy's supervisor could not explain why the volume was so high. During that time, Cardinal was the pharmacy's main distributor, and two of CVS's Florida pharmacies were among Cardinal's top four retail pharmacy customers, dispensing a staggering amount of oxycodone compared to Cardinal's other Florida customers. Interviews with employees of these pharmacies revealed that they routinely observed red flags and obvious signs that they were filling illegitimate prescriptions. One set a daily limit of oxycodone 30mg prescriptions the pharmacy would fill each day, basing the limit on the amount in stock that day, so as to ensure that the "real pain patients" could get their prescriptions filled.[43] The pharmacy usually reached its limit by lunchtime each day, and at times within 30 minutes of opening. Customers, aware that prescriptions were first come, first served, would line up outside the store as early as 7:45 AM. An employee acting as "bouncer" included escorting off the premises customers who were "hooked" on opioids and became belligerent if their prescriptions were refused among his job duties.[44] Although CVS had in place dispensing guidelines for controlled substances prescriptions, these guidelines were not followed at these stores. Rather, they dispensed controlled substances prescriptions despite clear red flags.[45]

204. Because of its vertically integrated structure, CVS has access to complete information regarding red flags of diversion across its pharmacies in and around the County, but CVS chose not to utilize this information and failed to effectively prevent diversion.

---

[43] Declaration of Joseph Rannazzisi, *Holiday CVS, LLC d/b/a CVS/Pharmacy Nos. 5195/219 v. Eric Holder, Jr. et al.*, No. 1:12-cv-191, Doc. 19-6 ¶¶ 38-41 (D.D.C. Feb. 24, 2012).
[44] *Id.* ¶ 41.d.
[45] *Id.* ¶¶ 48 & 56.

e. CVS Failed to Implement Effective Policies and Procedures to Guard Against Diversion from its Retail Stores.

205. By 2009, CVS Pharmacy, Inc. owned and/or operated more than 9,000 pharmacies in the United States. According to its website, CVS now has more than 9,900 retail locations. At all times relevant herein, CVS pharmacies sold controlled substances, including FDA Schedule II and FDA Schedule III controlled substances otherwise known as opiate narcotics or opioids.

206. "CVS Corporation," not any individual CVS store, is the DEA registrant for each of CVS's pharmacies across the country. CVS renews the DEA licenses for its pharmacies through a "Registration Chain Renewal." From October 2013 through December 2016, CVS headquarters paid more than $5 million to renew the licenses for 7,597 CVS locations, including a CVS in the County.

207. As described above, until October 6, 2014, CVS pharmacies ordered and were supplied FDA Schedule III hydrocodone combination products (HCPs) from a combination of outside vendors and CVS distribution centers. CVS pharmacies also received Schedule II opioids from outside vendors, with Cardinal acting as its exclusive outside supplier for the entire period for which ARCOS is available. Upon information and belief, McKesson also acts or has acted as an outside vendor for CVS.

208. CVS Pharmacy, Inc. instituted, set-up, ran, directed and staffed with its own employees the majority of the SOM functions for its pharmacy stores.

209. CVS also lacked meaningful policies and procedures to guide its pharmacy staff in maintaining effective controls against diversion, even as they evolved over time. Not until 2012 did CVS create guidelines explaining in more detail the "red flags" or cautionary signals that CVS pharmacists should be on the lookout for to prevent diversion and to uphold their corresponding

responsibilities to ensure that all dispensed controlled substances are issued for a legitimate medical purpose.

210. Even so, CVS's conduct, and the volume it dispensed in the County thereafter indicates that its policies were not applied. In addition, as discussed further below CVS had performance metrics in place that pressured pharmacists to put profits ahead of safety.

211. CVS failed to use data held at the corporate level to assist pharmacists in evaluating red flags of diversion. CVS's later dispensing policies and procedures make clear that for the majority of the time CVS has been engaged in the sale and dispensing of opioids, there was no meaningful integration of data and information that was within the possession and control of CVS corporate personnel.

212. Notably, with respect to CVS's suspicious order monitoring system for its wholesale distribution, the MDL Court has denied a motion for summary judgment contesting the evidence regarding the inadequacy of its SOM system in that litigation. *See* Opinion and Order [Denying CVS's Motion for Summary Judgment], MDL No. 2804, Doc.3099 (N.D. Ohio Jan. 27, 2020).

ii. Walgreens.

213. Acting as both a distributor and a retail pharmacy chain, Walgreens also self-distributed opioids to its own individual Walgreens pharmacies. Although Walgreens had visibility into red flags of diversion due to its vertically integrated distribution and dispensing practices, it failed to take these factors into account in its SOM program during the vast majority of the time it was distributing prescription opioids. Moreover, its program was wholly inadequate and did not fulfill its duties to prevent diversion. Likewise, Walgreens also failed to maintain effective controls against diversion from its pharmacy stores.

a. Walgreens Dragged Its Feet on Developing a SOMS Program, Instead Relying on After-the-Fact Reports of "Excessive" Orders While Ignoring Red Flags.

214. Though Walgreens had access to significant information about red flags due to its vertical integration with its stores, Walgreens failed to use available information to monitor and effectively prevent diversion.

215. At least as early as 1998, and perhaps as early as 1988, Walgreens began to utilize a series of formulas to identify orders that Walgreens deemed to be suspicious based on the orders' extraordinary size. These orders were listed on a report called the Suspicious Control Drug Order report.

216. Walgreens used two different formulas: one formula from (at least) 1998-2007 and one formula from March 2007 through 2012. These formulas were alike in that they each utilized an average number based on historical orders, applied a three times multiplier to that base number, and then deemed certain orders which were greater than that number to be suspicious. Under the later formula, orders were only listed on the report as being suspicious if the orders exceeded the three times multiplier for two consecutive months in a given time period. Walgreens based this second formula on the DEA's Chemical Handler's Manual's order monitoring system for listed chemicals.

217. The first variation on this formula was in place until March 2007, even though the DEA warned Walgreens that the "formulation utilized by the firm for reporting suspicious ordering of controlled substances was insufficient," *via* a May 2006 Letter of Admonition. The Letter cited Walgreens for controlled substances violations at its Perrysburg, Ohio Distribution Center, but highlighted problems that went far beyond that particular facility.

218. The DEA also reminded Walgreens that its suspicious ordering "formula should be based on (size, pattern, frequency)," though Walgreens failed to even examine anything other than

the size of an order. When Walgreens did update its program some ten months later, however, it still did not perform the size, pattern, and frequency analysis prescribed by the DEA, continuing to use another "three times" formula.

219. Even with its ample threshold, each Walgreens Suspicious Control Drug Order report could be thousands of pages or more in length.

220. Walgreens did not perform any due diligence on the thousands of orders identified as "suspicious" on the Suspicious Control Drug Order reports, but instead shipped the orders without review.

221. Walgreens did not report the suspicious orders listed on the Suspicious Control Drug Order report until *after* the orders were already filled and shipped. The report was generated on a monthly, nationwide basis, directly contravening the regulatory requirement that suspicious orders be reported *when discovered.* 21 C.F.R. 1301.74(b). In some instances, months may have elapsed between an order's shipment and its subsequent reporting to the DEA, given the requirement, described above, of two consecutive months of exceeding the three times multiplier to trigger reporting.

222. In September 2012, the DEA issued an immediate suspension order ("ISO") for one of Walgreens's three Schedule II distribution centers, finding Walgreens's distribution practices constituted an "imminent danger to the public health and safety" and were "inconsistent with the public interest." The DEA further found that Walgreens's Jupiter distribution center failed to comply with DEA regulations that required it to report to the DEA suspicious drug orders that Walgreens received from its retail pharmacies, resulting in at least tens of thousands of violations, particularly concerning massive volumes of prescription opiates. There, the DEA stated: "Notwithstanding the ample guidance available, Walgreens has failed to maintain an

adequate suspicious order reporting system and as a result, has ignored readily identifiable orders and ordering patterns that, based on the information available throughout the Walgreens Corporation, should have been obvious signs of diversion occurring at [its] customer pharmacies."

223. In the ISO, the DEA also specifically considered the Suspicious Control Drug Order reports and made the following further findings of fact and conclusions of law regarding the reports and Walgreens's suspicious order monitoring system—applicable across Walgreens's operations:

- "[Walgreens's] practice with regard to suspicious order reporting was to send to the local DEA field office a monthly report labeled 'Suspicious Control Drug Orders.'"
- "[The Suspicious Control Drug] reports, consisting of nothing more than an aggregate of completed transactions, did not comply with the requirement to report suspicious orders as discovered, despite the title [Walgreens] attached to these reports."
- Upon review of an example of the Suspicious Control Drug Order report for December 2011, "[Walgreens's] suspicious order report for December 2011 appears to include suspicious orders placed by its customers for the past 6 months. The report for just suspicious orders of Schedule II drugs is 1712 pages and includes reports on approximately 836 pharmacies in more than a dozen states and Puerto Rico."
- Finding that the reports failed to appropriately consider the population and area being served by the pharmacy: "This report from the Jupiter [Florida] Distribution Center covers pharmacies in multiple states and Puerto Rico, yet the average order and trigger amount is the same for a particular drug regardless of the pharmacy's location, the population it serves, or the number of other pharmacies in the area."
- "As made clear in 21 CFR§ 1301.74(b), *Southwood*, and the December 27, 2007 letter to distributors from the Deputy Assistant Administrator for the Office of Diversion Control, suspicious orders are to be reported *as discovered*, not in a collection of monthly completed transactions. Moreover, commensurate with the obligation to identify and report suspicious orders as they are discovered is the obligation to conduct meaningful due diligence in an investigation of the customer and the particular order to resolve the suspicion and verify that the order is actually being used to fulfill legitimate medical needs. This analysis must take place *before* the order is shipped. No order identified as suspicious should be fulfilled until an assessment of the order's legitimacy is concluded."

- "DEA's investigation of [Walgreens] ... revealed that Walgreens failed to detect and report suspicious orders by its pharmacy customers, in violation of 21 C.F.R. §1301.74(b). 21 C.F.R. § 1301.74(b)."

- ". . . DEA investigation of [Walgreens's] distribution practices and policies ... demonstrates that [Walgreens] has failed to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of 21 U.S.C. *55* 823(b)(l and (e)(l). [Walgreens] failed to conduct adequate due diligence of its retail stores, including but not limited to, the six stores identified above, and continued to distribute large amounts of controlled substances to pharmacies that it knew or should have known were dispensing those controlled substances pursuant to prescriptions written for other than a legitimate medical purpose by practitioners acting outside the usual course of their professional practice. . . . [Walgreens has not] recognized and adequately reformed the systemic shortcomings discussed herein."

- "[DEA's] concerns with [Walgreens'] distribution practices are not limited to the six Walgreens pharmacies [for which DEA suspended Walgreens' dispensing registration]."

b. Walgreens Knew its After-the-Fact Excessive Purchase Reports Failed to Satisfy Its Obligations to Identify, Report, and Halt Suspicious Orders.

224. Walgreens knew its procedures were inadequate well before the 2012 ISO issued. In addition to the guidance described above, in 1988, the DEA specifically advised Walgreens that "[t]he submission of a monthly printout of after-the-fact sales does *not* relieve the registrant of the responsibility of reporting excessive or suspicious orders." The DEA further advised Walgreens that, while "[a]n electronic data system may provide the means and mechanism for complying with the regulations...the system is not complete until the data is carefully reviewed and monitored by the registrant."

225. Despite this instruction, there is no evidence that Walgreens ever took any action related to the Suspicious Control Drug Order report besides generating it and mailing it out. Walgreens has admitted that there is no evidence that Walgreens ever performed a due diligence review on any of the orders listed on the Suspicious Control Drug Order report before shipment.

One of the managers for Walgreens's Pharmaceutical Integrity ("RX Integrity") Department stated that, when he was with the Loss Prevention Department, he "basically burned the data on a CD and sent it off. I didn't dive into each individual report or CD" and that he "would look at it briefly, but just to see if the data transferred to the CD, but that's about the extent."[46] In an errata submitted in connection with a deposition in the MDL, Walgreens acknowledged that it "is currently unaware of due diligence that was performed based on orders being flagged . . ."[47]

226. As described above, in May 2006, the DEA told Walgreens again that the formula Walgreens was using to identify suspicious orders for the Suspicious Control Drug Order reports was "insufficient" and "inadequate."

227. Moreover, in September 2007, three Walgreens's senior employees (Dwayne Pinon, Senior Attorney; James Van Overbake, Auditor; and Irene Lerin, Audit Manager) attended the DEA Office of Diversion Control's 13th Pharmaceutical Industry Conference in Houston, Texas. Michael Mapes, Chief, DEA, Regulatory Section, gave a presentation at this Conference relating to suspicious orders, which included the reminder that the CSA "requirement is to report suspicious orders, not suspicious sales after the fact." Participant notes from this meeting indicate that Mr. Mapes advised the audience not to "confuse suspicious order report with an excessive purchase report. They are two different things."

228. Similarly, handwritten notes on an internal document from July 2008 state that "DEA really wants us to validate orders and only report true suspicious orders or what was done to approve orders." They go on to state that "[j]ust reporting these orders is not good enough – need to document what happened."

---

46 E Stahmann Dep. at 287: 16-23.

47 *See* E. Bratton 30(b)(6) Dep. Erratum No. 3, Ex. 333.

229. Additionally, in November 2012, the Walgreens's Divisional Vice President of Pharmacy Services reported to Kermit Crawford, Walgreens's President of Pharmacy, Health and Wellness, his notes from meeting with the DEA about reporting suspicious orders, which included the note, "[i]f suspicious - you don't ship."

230. In a December 2008 Internal Audit of its Perrysburg Distribution Center, Walgreens admitted to systemic and longstanding failures in the systems surrounding DEA compliance:

> In our opinion internal controls that ensure compliance with DEA regulations at the Perrysburg DC require improvement. In addition, some of these issues pertain to all company DCs and should be addressed to avoid potential DEA sanctions. Specifically, our review found four issues previously cited in the DEA's May 2006 inspection report that are still open. In addition, four issues noted in our previous audit (report dated July 2005) remain un-remediated. Areas requiring the greatest level of improvement are as follows:
>
> DC-wide:
>
> - pseudoephedrine reporting requirements and inventory maintenance
> - suspicious controlled drug order processing and reporting
> - controlled drug reporting, specifically receiving record information
> - lack of formalized CII controlled substance policies and procedures.

231. The Internal Audit goes on to state that "Walgreens is required to have a process to disclose to the DEA any suspicious orders of controlled substances that deviate from the normal size, pattern, and frequency. Any orders that are deemed to be suspicious are required to be reported to the DEA upon discovery." It also notes that while "Walgreens produces monthly Suspicious Controlled Drug Orders report," the audit team recommended discussions continue across multiple departments within Walgreens regarding "reporting suspicious control drug orders" and an "Updated Suspicious Control Drug Order Identification Methodology," with an "Estimated Completion Date for the New Reporting" of "June 30 2009." In this respect, too, it

makes clear that the failures described are systemic. The audit also underlined Walgreens's lack of urgency in addressing the problems, indicating that the next "Cross-Functional Meeting" to address the "Updated Suspicious Controlled Drug Order Identification Methodology" would not occur for more than five months, at the end of May 2009.

b. Walgreens Lacked Meaningful Additional Systems to Address the Failures in Its System of After-the-Fact Reporting of Certain Orders.

232. Walgreens nominally employed additional procedures within its distribution centers; however, these systems did not address the failings of the Suspicious Control Drug Order reports. These distribution center systems were not designed to detect suspicious orders of controlled substances, but rather were designed to detect typos or errors in order entry by the stores. Walgreens admits that its Distribution Centers are "more akin to supply warehouses," are "not designed to be a backstop to pharmacists," and that they are not well "equipped to ensure compliance" or to "assist in combatting controlled substance abuse," and "do not have the ability to detect trends in local markets."

233. The Distribution Center ("DC") level procedures are documented in a 2006 Questionable Order Quantity policy, which had two facets: first, it instructed DC personnel to review orders and contact the pharmacy with questions regarding quantities. The policy did not mention reporting suspicious orders until 2010, when it was updated to state that the Corporate Office Internal Audit Department would handle suspicious store orders and inquiries. There is no evidence that the Internal Audit department had any involvement in reporting suspicious orders.

234. The second aspect of this DC level procedures required "pickers," the DC personnel who actually retrieved pill bottles off the shelves and placed them into totes for shipping, to look for "questionable" orders while picking.

235. The only review of the orders identified by the DC level procedures was calling the pharmacy to make sure the order had not been entered in error. Walgreens admitted this procedure was not intended to detect suspicious orders.

236. There is no evidence that any orders were ever reported as suspicious or halted as a result of Walgreens's distribution-center level policies. There is no evidence these procedures resulted in timely reporting of, due diligence on, or non-shipment of any order, including those listed as being "suspicious" on the Suspicious Control Drug Order reports.

237. Walgreens's documents effectively acknowledge that these were not true anti-diversion measures, and it recognized internally that it did not begin creating a suspicious order monitoring ["SOM"] system until March 2008. Specifically, in March 2008, Walgreens finally formed a five department "team" to "begin creating" a SOM program. The new SOM program was not piloted until more than a year later, in August 2009, and even then, the pilot included orders form just seven stores. Not until September 2010 would the program, implemented in pieces and phases, be rolled out chain-wide, and from that point it took several more years to fully implement.

238. Through 2012, Walgreens continued to populate the Suspicious Control Drug Order report with thousands of orders that exceeded Walgreens's "three times" test, showing that Walgreens's post-2009 SOM program did little to mitigate the extraordinary volume of controlled substances being shipped by Walgreens to its pharmacies.

c. Even as it Rolled Out its New SOM Program, Walgreens Left Significant Gaps and Loopholes in Place and Failed to Report and Perform Due Diligence on Orders It Flagged.

239. Walgreens did not prioritize compliance when instituting its SOM system. MDL testimony from the Senior Director of the Walgreen's Pharmaceutical Integrity Department, which is charged with supervising Walgreens's SOM system, revealed that even as late as 2012, 2013,

and 2014, Walgreens's viewed the SOM system as an inventory control mechanism rather than as a compliance control mechanism:

> Q: Now, Walgreens's system, similar to my alarm, is there to detect a potential red flag. Would you agree with that?
>
> A: It was put in place to ensure that the stores had the proper quantities. Not necessarily to . . . detect a red flag. The whole idea was to make sure that the stores were getting the quantities that they needed based on their peer group.

240. Perhaps because keeping supply moving, as opposed to preventing diversion, was Walgreens's primary focus, the SOM program Walgreens slowly developed had significant gaps or loopholes. For example, for the first few years, the program did not include orders that Walgreens stores were also placing to outside vendors, like Cardinal and AmerisourceBergen, allowing stores to order opioids from Walgreens distribution centers and from Cardinal and AmerisourceBergen, effectively permitting double dipping. It also did not prevent stores from placing an order to an outside vendor if the store attempted to place the order to a Walgreens DC, but was rejected by the new SOM system.

241. The new SOM-lite system also allowed Walgreens's stores to transfer controlled substances between stores and did not review these transfers (known as "interstores") within the SOM program, so that these transfers were not factored into SOM analytics. Additionally, stores could also place ad hoc "PDQ" ("pretty darn quick") orders for controlled substances outside of their normal order days and outside of the SOM analysis and limits. Walgreens could even remove a store entirely from SOM review.

242. Further, although the new SOM algorithm identified more than 389 pages of suspicious orders per week as of August 2010, it failed to identify all the orders that Walgreens had marked as suspicious under its "three times" formulas and previously listed on its Suspicious Control Drug Order reports and submitted to the DEA "on a monthly basis." This "discrepancy"

prompted an internal email from an employee in Walgreens's Loss Prevention Department, to Walgreens's Vice President, Distribution Centers and Logistics, suggesting that "the new system should be tested further and enhanced to provide broader coverage of controlled substance activity. The same e-mail stated that "we are not equipped to handle the 389+ pages of ADR4 [suspicious order monitoring] data which are compiled nationwide each week," and asked if his department had "a resource available" to assist. An email in response "recall[ed] the old paper report as being inches thick" and an instruction "in 1985 not to review or contact anyone on the data," and inquired, among other things, "[w]ho from your group has been reviewing the data collected for the past twenty-five years?" and "[a]t present is anyone doing any review on what would be considered suspicious quantities that are physically ordered and are releasing to stores?"

243. Starting in 2010, certain orders that exceeded store-based limits imposed by Walgreens's new SOM system were reduced to the store limit and shipped out. These orders were not reported to the DEA as suspicious, nor were they halted for review. The DEA found that Walgreens's policy of reducing and then filling and shipping suspicious orders without reporting them violated the law:

> This policy ignores the fact that the reporting requirement of 21 CFR § 1301.74(b) applies to *orders,* not shipments. A suspicious order placed by a customer pharmacy is made no less suspicious by application of a system designed to reduce or eliminate such orders prior to shipping. Construing the regulation this way defeats the essential purpose of the suspicious order requirement, which, as I stated in *Southwood,* is "to provide investigators in the field with information regarding potential illegal activity in an expeditious manner." 72 FR at 36501.

244. Walgreens's post-2009 SOM system flagged thousands of items per month as being suspicious. Internal Walgreens documents indicate that, in July 2011 alone, as many as 20,699 orders for controlled substances were "marked suspicious" by the new algorithm. However, very few of these orders received any review, and any review performed was nominal at best.

Meanwhile, Walgreens failed to adequately staff the program and to train its employees regarding its requirements.

245. Walgreens cited two people as being primarily responsible for performing due diligence on suspicious orders in the 2009-2012 time period under the new SOM system. The first was a representative from the Loss Prevention department who said her department was "not equipped" to handle review and data analysis for the hundreds of pages of reports being compiled nationwide each week. The second was Barbara Martin, who estimated that she spent somewhere between one and three hours a week reviewing suspicious orders, reviewing only between 10 to 100 of the thousands of orders that were deemed suspicious under the new algorithm. Walgreens did not provide Ms. Martin access to information about the area the store was serving, the order history for comparable stores, or any other data beyond the sales and order history for that store. If an order did not "make sense" to her based on those limited resources, she testified that she would call the store or district manager or pharmacy supervisor. She lacked authority to take "direct action" on an order.

246. Walgreens has previously cited to a series of email exchanges with Ms. Martin and her deposition testimony as exemplars of its due diligence procedures under the post-2009 SOM program. In the emails, which date from January 10-11, 2011 and are between Ms. Martin and a Walgreens Distribution Center ("DC") employee, the DC employee notes that "several stores that are ordering huge quantities of 682971 [30 mg oxycodone] on a regular basis." The DC employee continued, with respect to a single store, "we have shipped them 3271 bottles [of 30 mg oxycodone] between 12/1/10 and 1/10/11. I don't know how they can even house this many bottles to be honest. How do we go about checking the validity of these orders?" Ms. Martin noted that the store had average weekly sales of 36,200 dosage units, which was equal to 362 bottles per

week, stating, "I have no idea where these stores are getting this type of volume. The last pharmacy I was manager at did about 525 rxs/day and we sold about 500 tabs a month (5 bottles)." Ms. Martin then told the DC employee that she could call the district pharmacy supervisor to see if he "may be able to shed some light on the subject." Despite the fact that questions had been raised about this store ordering volume in January 2011, the very next month, Walgreens filled and shipped orders totaling another 285,800 dosage units of 30 milligram oxycodone to the same pharmacy, which was located in a town of less than 3,000 people.

247. In her deposition, Ms. Martin stated that she never even attempted to determine the size of the community that was receiving these "huge quantities" of oxycodone. She further testified that she was not near that store, did not have access to the store's prescriptions or patient information, and as noted above, couldn't take any "direct action." Approximately 18 months after this email exchange, as a result of DEA action, Walgreens agreed to surrender its DEA registration for this same store that Ms. Martin reviewed as part of her exemplary "due diligence."

248. In the ISO regarding the Distribution Center, the DEA found specifically regarding the orders that were the subject of these email exchanges, that "[b]ased on the evidence available to DEA, none of these orders were reported to DEA as suspicious and all appear to have been shipped, without any further due diligence to verify their legitimacy." The DEA further found regarding this purported "due diligence," that Walgreens "failed to conduct any meaningful investigation or analysis to ensure that the massive amounts of commonly abused, highly addictive controlled substances being ordered by these pharmacies were not being diverted into other than legitimate channels." The DEA noted that "[Walgreens] has been unable to provide any files related to any effort to adequately verify the legitimacy of any particular order it shipped to its customer stores."

249. These failures were not limited to the specific Florida pharmacies and distribution center described above; instead, they reflect systemic failures of Walgreens's SOM system that impacted its distribution in the County, as well. Walgreens admits that the SOM systems and procedures at all of its DCs were the same, including those at the facilities that continued shipping opioids into the Plaintiff County. Accordingly, it is not surprising that, in February 2013, the DEA issued similar Subpoenas and Warrant of Inspection on the Perrysburg DC in Ohio to those issued to the Jupiter DC in Florida. Walgreens employees made plans in preparation for the Perrysburg DC being "shut down" by the DEA, like the Jupiter DC. Within weeks of receiving the six subpoenas and warrant, Walgreens decided to "discontinue distribution of controlled substances from the Perrysburg facility" in order to "eliminate any immediate need for further DEA administrative action" regarding the Perrysburg facility.

250. Walgreens has admitted that both the Florida and Ohio DCs distributed prescription opioids into Ohio.

251. Further, after the DEA began its investigation, Walgreens held meetings with and informed the DEA that it was implementing "new changes" to "enhance" its SOM program. Internal documents reveal that Walgreens improved its SOM program only "in an effort to convince the DEA that the proposed penalty is excessive."

252. Even so, by November 2012, the program still did not halt the orders for due diligence evaluation or report the orders as suspicious. Further, at that time, the program began to automatically reduce orders that violated ceiling thresholds.

253. There also is no evidence that these flagged or cut orders were reported as suspicious to the regulatory authorities.

254. As a result of the DEA investigation, Walgreens formed the Pharmaceutical Integrity ("Rx Integrity") Team in 2012, purportedly to make sure that those types of failures did not continue. However, the group's true role was protecting Walgreens's Distribution Centers and stores from losing their DEA licenses. The effort was only for show. Walgreens never provided the Rx Integrity group the resources needed to achieve due diligence on the large number of orders identified by Walgreen's SOM program for the company's 5,000 plus stores.

255. In December 2012, the further enhanced SOM system flagged "14,000 items that the stores ordered across the chain that would have to be investigated" before they could be shipped. [48] Walgreens admitted that yet again it did not have sufficient resources to timely review these orders. Walgreens noted that "[t]he DEA would view this as further failures of our internal processes, which could potentially result in additional pharmacies and distribution centers being subjected to regulatory actions and ultimately prohibited from handling controlled substances." At the time these 14,000 orders were flagged Walgreens Rx Integrity Team was comprised of fewer than five people. [49] Even at its height, Rx Integrity had only eleven employees. Instead of sufficiently staffing the SOM program, Walgreens recognized it had the ability to control its due diligence workload by increasing the stores' ceiling levels, and thereby reducing the number of orders that would hit that ceiling and result in a flag.

256. As described below, Walgreens admits to failures in its suspicious order monitoring prior to 2012. Comparing the 2013 SOM system to the previous system, one of Walgreens's Pharmaceutical Integrity Managers in August 2013 explained:

> The Controlled Substances Order Monitoring system now in place sets limits for each item based on the chain average for that item for stores of similar size. If a particular store fills more of this item than normal and needs additional product we

[48] WAGMDL00659270.
[49] Polster Dep., at 240:3-15.

> would need to document the reason and increase via a CSO Override .... The purpose for this is to ensure we have performed adequate review before sending in additional inventory.
>
> **The previous system would continue to send additional product to the store without limit or review which made possible the runaway growth of dispensing of products like Oxycodone, that played a roll [sic] in the DEAs investigation of Walgreens**.[50]

257. Yet, even in 2013, orders being flagged as suspicious for review before shipment were "a week old" before they made it to the review team, often "ha[d] already been shipped," and were not being reported.

258. Walgreens never equipped its distribution operations to monitor, report, and halt suspicious orders, or otherwise effectively prevent diversion. When it became clear Walgreens would need to devote significant resources to achieve compliance, Walgreens chose instead to cease controlled substance distribution all together. Walgreens stated that "while the financial impact of no longer . . . [self distributing] from the Walgreens DCs was taken into consideration, there is a greater risk to the company in fines and loss of licenses if we continue to sell these items in our warehouses."

259. Indeed, with respect to Walgreens's suspicious order monitoring system for its wholesale distribution, the MDL Court has denied a motion for summary judgment contesting the evidence regarding the inadequacy of its SOM system in that litigation. *See* Order [Denying Walgreen's Motion for Summary Judgment], MDL No. 2804, Doc. 2569 (N.D. Ohio Sept. 4, 2019).

e. Walgreens Failed to Put in Place Adequate Polices to Guard Against Diversion at the Pharmacy Level.

[50] WAGMDL00021425 (emphasis added).

260. Although Walgreens purported to have in place "Good Faith Dispensing" ("GFD") Policies for many years, it failed to meaningful apply policies and procedures, or to train employees in its retail pharmacies on identifying and reporting potential diversion.

261. Despite knowing that prescribers could contribute to diversion, and having a separate and corresponding duty with respect to filling prescriptions, from at least 2006 through 2012, Walgreens's dispensing policies, which it titled "Good Faith Dispensing", or "GFD", explicitly instructed pharmacists who "receive[] a questionable prescription" or otherwise were "unable to dispense a prescription in good faith" to "contact the prescriber" and, if "confirm[ed]" as "valid" by the prescriber, to then "process the prescription as normal." Further, though Walgreens's policies listed a handful of "questionable circumstances," such as "increased frequency of prescriptions for the same or similar controlled drugs by one presciber[,] for large numbers of patients [,] for quantities beyond those normally prescribed," it is unclear what, if any, resources Walgreens made available to its pharmacists for checking these vague criteria, which, in any event, became meaningless if a prescriber "confirm[ed]" the prescription as "valid," by calling the prescriber. For example, in 2010 when a pharmacy manager expressed concern about significant numbers of opioid prescriptions from pain clinics, and being help responsible for "excessive c2 rx dispensing," her district supervisor instructed her "not [to] refuse script for large quantities" but simply to "call the MD's, document it on the hard copy[,] and that is all that is needed to protect your license." Despite internally recognizing that "a prescriber of a controlled substance prescription [may be] involved in diversion", Walgreens's GFD policies continued to endorse calling the doctor as a greenlight to any "questionable" prescription.

262. In 2012, Walgreens finally removed the "process the prescription as normal" language from its formal GFD policies, admitting that under the law "it is not enough to get

confirmation that the prescriber wrote the prescription." However, Walgreens still failed to ensure it complied with its duties.

263. Upon information and belief, Walgreens failed to adequately train its pharmacists and pharmacy technicians on how to prevent diversion, including what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when other suspicious circumstances are present. To be clear, this required no inquiry into whether an opioid prescription was the proper treatment for a particular patient; instead, as a registrant, Walgreens was obligated, and failed, to implement policies and procedures at a corporate level to identify and address signs of diversion. *Compare United States v. Hayes*, 595 F.2d 258 (5th Cir. 1979) ("It is also evident that a pharmacist can fulfill his responsibility under s 1306.04 without practicing medicine. The facts of this case show how a pharmacist can know that prescriptions are issued for no legitimate medical purpose without his needing to know anything about medical science.").

264. Indeed, during the course of a 2009 DEA investigation into Walgreens dispensing noncompliance, Walgreens internally noted that it currently had "no training" for employees dispensing controlled substances. Meanwhile, Walgreens corporate officers turned a blind eye to these abuses. In fact, a Walgreens corporate attorney suggested, in reviewing the legitimacy of prescriptions coming from Florida, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens's attitude that profit outweighed compliance with the law or protecting public health.

265. Ultimately, in 2011, Walgreens and the DEA entered a Memorandum of Agreement regarding all "Walgreens . . . pharmacy locations registered with the DEA to dispense controlled substances," requiring Walgreens to implement significant nationwide controls lacking in its

operations. Walgreen Co. was required to create a nationwide "compliance program to detect and prevent diversion of controlled substances ***as required by the … (CSA) and applicable DEA regulations***." Pursuant to the MOA, the "program shall include procedures to identify the common signs associated with the diversion of controlled substances including but not limited to, doctor-shopping and requests for early refills" as well as "routine and periodic training of all Walgreens walk-in, retail pharmacy employees responsible for dispensing controlled substances on the elements of the compliance program and their responsibilities under the CSA." Further, Walgreens was required to "implement and maintain policies and procedures to ensure that prescriptions for controlled substances are only dispensed to authorized individuals pursuant to federal and state law and regulations."

266. Walgreens would also make more promises in a 2013 MOA with the DEA, described further below, related to failures to that lead to the ISOs described above.

267. Even after development and a relaunch of its GFD policy in response to settlements with the DEA, however, Denman Murray, Director of Rx Supply Chain Retail, stated in an MDL deposition that, "traditionally, we've always treated a controlled substance like any other, [a] widget's a widget to the system."

268. Further, after the GFD "relaunch" in April 2014, a Walgreens "RxIntegrity" presentation focused on Walgreens "Market 25," but also assessing "average market" trends, reported that "pharmacists [were] not being too strict with GFD, nor [were] they losing volume."[51]

269. As with distribution, Walgreens failed to allocate appropriate resources to dispensing compliance and supervision. Walgreens has approximately 26,000 pharmacists, each

[51] Market 25 consisted of Indiana, Kentucky, and West Virginia. Similar results reported for Market 3, Florida.

of whom may receive as many as 400-500 prescriptions a day. In 2013, however, Walgreens internally reported that its District Managers and Pharmacy Supervisors were "challenged to get into the stores" and in a 90-day period, more than a thousand stores did not receive a visit from the managers or supervisors. These supervisory personnel were assigned a "high number of stores" and their time was consumed with "people processes, business planning, market and district meetings," such that supervision in store was being handled informally by "community leaders" who have "limited formal authority."

270. A Walgreens internal audit performed after the 2013 DEA settlement confirms that Walgreens's supervision and compliance failures continued. Among other failings, the audit team noted no formal monitoring program existed to confirm that pharmacies across the chain are complying with controlled substance documentation and retention requirements, no monitoring outside of the deficient "store walk program" existed to monitor target drug good faith dispensing requirements and no corporate reporting was being generated, and employees were failing to timely complete Good Faith Dispensing training, such that, at the time of the audit, over 35,000 employees had not completed their required training for that year. Management's response largely was to seek to incorporate additional compliance measures into the store walk procedure. However, documents from 2016 regarding monthly store compliance walks indicate that during the monthly "Compliance Walks" to "verify compliance … [with] regulatory requirements in… pharmacy areas," substantially no dispensing compliance supervision occurred, outside of ensuring the pharmacy was verifying the patient's address on five sample prescription fills.

271. Unsurprisingly, compliance with GFD and TD GFD has been poor. For example, in 2014 Walgreens discovered a pharmacist who failed to follow GFD for five to six months without being discovered by supervisors. In 2014, Rx Integrity noted dozens of stores dispensing

opioids without performing the required checks. In certain cases, the pharmacists were unaware of the GFD procedures or had been told by supervisors to disregard them.

272. In 2015, Walgreens performed a "business continuity" audit of a random sample of approximately 2,400 pharmacies to determine whether Walgreens was "compliant with the policies/procedures put in place" regarding dispensing pursuant to Walgreens's agreement with the DEA. In Walgreens's own words, "Results were unfavorable." Fewer than 60% of stores were complying with TD GFD with respect to filled prescriptions, 1,160 stores did not have a single refused prescription, and an additional 1,182 stores had refused fewer than 25 prescriptions total in a nine-month period. Only 63 out of 2,400 pharmacies had refused 26 or more prescriptions during that same nine months in 2015.

f. Walgreens Assumed Greater Responsibility for Controlling Against Diversion by Discouraging Outside Vendors from Exercising Their Own Oversight.

273. The "Big Three" wholesalers, Cardinal, McKesson, and AmerisourceBergen, gave deferential treatment to chain pharmacies, such as Defendants. An internal Cardinal document for example, stresses that "certain chain pharmacies refuse to allow any sort of administrative inspection by Cardinal or to make certifications" and that large, national chains can "take their billions upon billions of dollars in business to any wholesaler in the country."

274. Thus, for example, in 2008, Cardinal prepared talking points for a NACDS Conference about its planned retail chain SOM program, making it clear that the program would "minimize the disruption" to retail chains and that they would "work together" with the pharmacies " to ensure that our Suspicious Order Monitoring program for retail chains does not interrupt" business. Cardinal also provided warnings to chain pharmacies, including Walgreens, that they were approaching thresholds so that the chains could avoid triggering SOM reporting and adjust ordering patterns by, for example, delaying orders or, more often, obtaining a threshold increase.

Such "early warnings" were so helpful to Walgreens that as of 2012 Walgreens adopted the concept for its own SOM system for self-distribution, noting internally that by "flagging the stores at 75%," it could "avoid cutting/reducing orders and subsequently not have to report a SOM to the DEA."

275. Preferential treatment of Walgreens ultimately was not enough for Cardinal to keep Walgreens's business, however. In 2013, Walgreens entered a ten-year agreement with AmerisourceBergen Drug Company. The shift to AmerisourceBergen as its exclusive supplier prompted Cardinal to complain: "we bailed you guys out when you had your [DEA] issues."

276. By 2017, Walgreens accounted for 30% of AmerisourceBergen's revenue. AmerisourceBergen was similarly deferential, allowing Walgreens to "police their own orders and block any order to [AmerisourceBergen ("ABC")] that would exceed ABC's threshold thus triggering a suspicious order being sent to DEA from ABC. Additionally, when AmerisourceBergen received orders from Walgreens "outside the expected usage," Walgreens and AmerisourceBergen met to discuss adjusting thresholds or using "soft blocking." Contrary to DEA guidance and its own stated policy, AmerisourceBergen also shared the threshold limits set by its "order monitoring program" with Walgreens, and also provided Walgreens with weekly SOM statistics. AmerisourceBergen generally would not take action on Walgreens orders that exceeded its thresholds without first talking to Walgreens.[52]

277. Walgreens also owns 26% of AmerisourceBergen's stock. In 2018, after a coalition of AmerisourceBergen shareholders sought greater transparency from its Board related to the "financial and reputational risks associated with the opioid crisis," Walgreens, together with other

[52] Rite Aid received similar accommodations from McKesson, which forwarded it dialed monitoring reports so that Rite Aid could "let [McKesson know] if it needed to make any adjustments to its thresholds. MCKMDL00646634.

insiders, reportedly leveraged this position to defeat the proposal, which enjoyed majority support among the independent shareholders.

g. Walgreens Failed to Maintain Effective Controls Against Diversion in the County.

278. As described above and further below, as both a distributor and a dispenser, Walgreens ignored red flags of diversion in Ohio and the County.

279. In the County, as a distributor, Walgreens shipped more than ***13.1 million*** dosage units of oxycodone and hydrocodone. Even this supply, however, was not enough for its six stores in the County. In total, at the pharmacy level, Walgreens purchased more than ***15.6 million*** dosage units of oxycodone and hydrocodone shipped to seven pharmacies from 2006 to2014.

280. Further, analysis of ARCOS data also reveals that one Lake County Walgreens alone purchased more than 3.8 million dosage units of oxycodone and hydrocodone from 2006 to 2014, and two other Lake County Walgreens purchased more than 3.2 million dosage units and 2.4 million dosage units of these drugs, respectively, during the same time frame. The highest-buying Walgreens in the County during this time purchased enough oxycodone and hydrocodone for approximately 19 pills per year for each of the 22,259 people who live in the city of Willoughby – notwithstanding the fact that, as described above, there was also a CVS located only a half a mile away that flooded the same area with over 4.5 million dosage units of these drugs during the same time period, and at least nine additional pharmacies within a five-mile radius of these high-buying Walgreens and CVS locations.

281. Walgreens violated the standard of care for a distributor by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities it knew or should have known could not be justified and signaled potential diversion.

282. The volume of opioids Walgreens shipped into, and dispensed from locations in, the County was so high as to raise a red flag that not all of the prescriptions being ordered could be for legitimate medical uses.

283. Yet, upon information and belief, Walgreens did not timely report any suspicious order in the County between 2007 and 2014**.** Instead, Walgreens funneled far more opioids into Ohio and the County than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. This information, along with the information known only to distributors such as Walgreens (especially with its pharmacy dispensing data), would have alerted Walgreens to potential diversion of opioids.

284. In addition, Walgreens also distributed and dispensed substantial quantities of prescription opioids in other states, including Florida, as described above, and these drugs were diverted from these other states to Ohio. Walgreens failed to take meaningful action to stop this diversion despite its knowledge of it, and it contributed substantially to the opioid epidemic in Ohio and in the County.

285. Walgreens knew the flood of pills being supplied into Florida were being diverted into Ohio. For example, a DEA presentation Walgreens produced as part of discovery in the MDL specifically ties this "Florida Migration" to Ohio, stating that the "[v]ast majority of 'patients' visiting Florida 'pain clinics' come from out of state: . . . [including] Ohio." Walgreens also knew that the DEA was conducting a "crackdown on Florida pharmacies where the market is notorious for illicit prescription painkillers" and that Walgreens's own pharmacies accounted for 53 of the top 100 retail sellers of oxycodone in Florida. Walgreens knew as well that these pills being sold into the "epicenter[s] of [the] notorious well-documented epidemic of prescription drug abuse… were migrating to other states," and that many "prescriptions [were] not for a legitimate medical

purpose." Walgreens also received presentations highlighting an Ohio drug ring's trips to Florida to get pills, and significant volumes of opioid prescriptions from Florida doctors for Ohio and Kentucky patients being filled in Ohio.

286. Walgreens also developed and maintained highly advanced data collection and analytical systems. These sophisticated software systems monitor the inventory and ordering needs of customers in real-time and depicted the exact amounts of pills, pill type, and anticipated order threshold for its own stores.

287. Through this proprietary data, Walgreens had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids in Ohio, including in the County. It used this data to evaluate its own sales activities and workforce. Walgreens also was in possession of extensive data regarding individual doctors' prescribing and dispensing to its customers, the percentage of a prescriber's prescriptions that were controlled substances, individual prescription activity across all Walgreens stores, and the percentages of prescriptions purchased in cash. Such data are a valuable resource that Walgreens could have used to help stop diversion, but it did not.

288. Upon information and belief, Walgreens, by virtue of its data analytics, was actually aware of indicia of diversion, such as (1) individuals traveling long distances to fill prescriptions; (2) prescriptions for drug "cocktails" known for their abuse potential, such as oxycodone and Xanax; (3) individuals who arrived together with identical or nearly identical prescriptions; (4) high percentage of cash purchases; and (5) doctors prescribing outside the scope of their usual practice or geographic area. However, Walgreens ignored these obvious red flags.

289. Upon information and belief, based on other enforcement actions against the company, Walgreens also failed to adequately use data available to it to identify doctors who were

writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts or doses of opioids, or to adequately use data available to it to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

290. Upon information and belief, Walgreens failed to analyze: (a) the number of opioid prescriptions filled by its pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; and (c) the number of opioid prescriptions filled relative to other drugs.

291. Upon information and belief, based on other enforcement actions against the company, Walgreens also failed to conduct adequately analyze and address its opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if it conducted such reviews, it failed to take any meaningful action as a result.

292. Discovery will reveal that Walgreens knew or should have known that its pharmacies in Ohio, and the surrounding area, including West Virginia, Michigan, and Kentucky, were (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription "cocktails"; (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-

controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets. Walgreens had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

293. Walgreens admits its role in the opioid epidemic, stating it has the "ability – and [] critical responsibility – to fight the opioid crisis" as the "nation's largest pharmacy chain" in a time when "[a]ddiction to prescription painkillers, heroin, and other opioids has surged, with opioid overdoses quadrupling in this decade" and "drug overdose deaths – the majority from prescription and illicit opioids" resulting in "more fatalities than from motor vehicle crashes and gun homicides combined." Walgreens also admits the "opioid crisis" is caused by "misuse, abuse and addiction" that result from the "flow of opioids that fuel the epidemic."

iii. Rite Aid

a. Rite Aid. Failed to Maintain Effective Controls Against Diversion at the Wholesale Level.

294. Rite Aid distributed Schedule III ("CIIIs") controlled substances (*e.g.*, hydrocodone combination products) to its own Rite Aid stores until late 2014. Rite Aid distributed to the County through its Perryman Distribution Center (Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center) and its Liverpool Distribution Center (Eckerd Corporation d/b/a Rite Aid Liverpool Distribution Center), both DEA registrants.

295. Rite Aid's controlled substance distribution process was fairly simple. Rite Aid used a computerized "auto-replenishment system" (ARS) through which individual Rite Aid pharmacies would generate orders that were sent to the distribution center (DC). This ARS relied directly on dispensing data and the dispensing patterns of individual Rite Aid stores. If the ARS generated an order that was above Rite Aid's universal 5,000 dosage-unit (DU) threshold, the DC

employees filling the order were supposed to manually recognize that the order was above threshold. If they did observe an order over threshold, the only "review" of the order was an attempt to call the pharmacy that placed the order to verify the order amount was correct (*i.e.*, that it was not a "fat-finger" error). If the pharmacy confirmed that the above-threshold order amount was correct, or if the DC simply could not contact the pharmacy, the order was cut to the threshold and shipped. All the above-threshold orders were supposed to be maintained on a handwritten log containing only basic information about the order.

296. After the orders had shipped, Rite Aid monitored its inventory through its Navicase/Naviscript system. The Rite Aid Asset Protection Department used "key performance indicators" (KPIs) to analyze data about ordering from the Rite Aid stores to identify diversion through theft. Yet, as numerous Rite Aid witnesses have testified, Rite Aid did not use the Navicase/Naviscript system to identify—much less report—suspicious orders. Furthermore, assuming that the Navicase/Naviscript could identify suspicious orders, the Navicase/Naviscript data analysis only took place *after* shipment. Moreover, Rite Aid's 30(b)(6) representative in the MDL, Janet Getzey Hart, testified that the "asset protection KPIs were utilized to review orders and then lead to diversion cases if there were some issues with it," but "*they were not used to report suspicious orders*."

297. Rite Aid maintained a small, inadequate list of suspicious prescribers but did not make any efforts to identify or report any suspicious orders from stores Rite Aid knew were dispensing prescriptions for those suspicious prescribers. Further, given that orders would have already shipped, Rite Aid did not incorporate "suspicious prescriber" information that it may have collected in determining whether an order from any location was suspicious.

298. Ultimately, Rite Aid's distribution system made it nearly impossible for any order to be identified, much less reported, as suspicious. As a result of the company's policies and procedures, Rite Aid did not – and indeed, could not – identify what was unusual because all Rite Aid DCs had a static, blanket threshold for all Rite Aid stores above which Rite Aid would cut the order. The threshold, which never changed, was set at of 5,000 DUs, per national drug code (NDC), per order (although Rite Aid does not know why it was set at 5,000 DUs). Rite Aid stores typically ordered once per week, but some stores ordered twice per week and others ordered every two weeks. That means that at its lowest, the Rite Aid threshold was 10,000 DUs per month, per store and at its highest it was 40,000 DUs per month, per store.

e. Despite the extremely high threshold amount, Rite Aid did not have a procedure that required anyone to report an order that came in over the universal threshold as suspicious. Instead, DC employees would "cut" the order down to the threshold and then ship the order. Rite Aid did no due diligence on orders that came in over the blanket threshold. An overwhelming number of the "cut" orders, if not all, were not reported to the DEA until after the fact, if at all.

299. Rite Aid also had little to no records about past order history to determine if an order was suspicious. The Perryman DC kept what was called a "Threshold Log," which contained in hard copy only basic information about orders that exceed the threshold: date of order, store number, item number, item description, quantity ordered, allowable quantity, and the reason for the allowable quantity. But, any use of the log to potentially identify suspicious orders was only done sporadically and after the above-threshold orders were cut and shipped.

300. Additionally, Rite Aid placed the responsibility to identify orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency on

employees whom the DEA coordinator at the Rite Aid's distribution center, testified were not able to actually do so.

301. Recognizing its failure to have a system, Rite Aid did begin to develop a suspicious order monitoring system for the first time in 2013. In documenting such efforts, Rite Aid stated as follows:

> *The purpose of this project is to develop effective controls against the diversion of controlled substances* and conduct adequate due diligence to ensure that controlled substances distributed from the Distribution Centers are for legitimate patient needs. Rite Aid must ensure compliance with 21 U.S.C. 823 and/or C.F.R. 1307.74(b) to detect and report suspicious orders of controlled substances through the Distribution Centers.

In the end, however, Rite Aid never adopted the new SOM system because it stopped distributing controlled substances before this system could be implemented.

302. With respect to Rite Aid's suspicious order monitoring system for its wholesale distribution, the MDL Court has denied a motion for summary judgment contesting the evidence regarding the inadequacy of its SOM system in that litigation. *See* Opinion and Order [Denying Rite Aid's Motion for Summary Judgment], MDL No. 2804, Doc. 3100, 2020 WL 425940 (N.D. Ohio Jan. 27, 2020).

b. Rite Aid Conspired with McKesson to Avoid Scrutiny of Outside Vendor Orders and Adjust or Avoid Thresholds.

303. Rite Aid conspired with McKesson to avoid suspicious order reporting. McKesson was Rite Aid's exclusive wholesaler for Schedule II controlled substances, including opioids, during the relevant time period. Rite Aid also ordered CIIIs from McKesson during the relevant time period. Rite Aid ordered CIIIs from McKesson not only when it stopped self-distributing in late 2014, but McKesson also supplemented Rite Aid stores' supply of Schedule III controlled substances during the period when Rite Aid self-distributed controlled substances.

304. McKesson provided Rite Aid with notification of stores hitting McKesson's thresholds and regularly granted threshold increases without conducting any due diligence. For example, when a McKesson report revealed a number of Rite Aid stores were at 90% of their threshold and about to be flagged, McKesson offered to – and did - increase the thresholds for *all* Rite Aid locations by 50%. McKesson also forwarded daily monitoring reports to Rite Aid so that Rite Aid could "let [McKesson] know" if McKesson "need[ed] to make any adjustments to current thresholds."

305. On one occasion, Rite Aid noted that over 10% of its stores came close to being blocked, and McKesson simply asked Rite Aid how high it wanted the thresholds increased. McKesson also prompted Rite Aid to delay its orders until the next month in order to avoid hitting monthly thresholds when they were getting close.

306. A striking example of Rite Aid's collaboration with McKesson to avoid suspicious order reporting occurred in Ohio. Customers of Dr. Adolph Harper. Dr. Harper, now in prison, is an ob-gyn who prescribed opioids at shocking volumes and doses to patients who included large numbers of men, who frequented Rite Aid stores to fill their prescriptions. Rite Aid worked with McKesson to ensure an increase in the amount of opioids Rite Aid could order from McKesson specifically to meet the illegitimate demand from Dr. Harper. Neither Rite Aid nor McKesson reported any of these orders as suspicious.

307. Rite Aid allowed its stores to order from McKesson without any restriction and failed to take those orders into account in Rite Aid's self-distribution SOM system, negating any constraints from Rite Aid's even limited internal controls

c. Rite Aid Failed to Guard Against Diversion in Distributing to the County.

308. In the County, Rite Aid violated the standard of care for a distributor by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities it knew or should have known could not be justified and signaled potential diversion.

309. Rite Aid self-distributed more than ***1.6 million*** dosage units, of oxycodone and hydrocodone from 2006 to 2014 to pharmacies in the County, the years for which ARCOS data is available. The volume of opioids Rite Aid shipped into, and dispensed from locations in, the County is so high as to raise a red flag that not all of the prescriptions being ordered could be for legitimate medical uses.

310. Rite Aid funneled far more opioids into Ohio and the County than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. This information, along with the information known only to distributors such as Rite Aid (especially with its pharmacy dispensing data), would have alerted Rite Aid to potential diversion of opioids. Yet, Rite Aid admits that it *never* identified any suspicious orders before or after shipment, much less reported any suspicious orders to the DEA.

311. Upon information and belief, Rite Aid, by virtue of the data available to it, was actually aware of indicia of diversion, such as (1) individuals traveling long distances to fill prescriptions; (2) prescriptions for drug "cocktails" known for their abuse potential, such as oxycodone and Xanax; (3) individuals who arrived together with identical or nearly identical prescriptions; (4) high percentage of cash purchases; and (5) doctors prescribing outside the scope of their usual practice or geographic area. However, Rite Aid ignored these obvious red flags.

312. Rite Aid therefore, was aware of the suspicious orders that flowed from its distribution facilities. Rite Aid refused to identify, investigate, and report suspicious orders despite

its actual knowledge of drug diversion. Rather, Rite Aid failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids flowing into Ohio and the County.

313. Upon information and belief, Rite Aid failed to analyze: (a) the number of opioid prescriptions filled by its pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; and (c) the number of opioid prescriptions filled relative to other drugs.

314. Rite Aid was, or should have been, fully aware that the opioids it distributed and dispensed were likely to be diverted; yet, it did not take meaningful action to investigate or to ensure that it was complying with its duties and obligations with regard to controlled substances, including its responsibility to identify and report suspicious orders and not to ship such orders unless and until due diligence allayed the suspicion.

315. Given Rite Aid retail pharmacy operations, in addition to its role as a wholesale distributor, Rite Aid knew or reasonably should have known about the disproportionate flow of opioids into Ohio and the County and the operation of "pill mills" that generated opioid prescriptions that, by their quantity or nature, were red flags for, if not direct evidence of, illicit supply and diversion.

d. Rite Aid Failed to Guard Against Diversion in Dispensing to the County.

316. Rite Aid pharmacies routinely have dispensed opioids in violation of the Controlled Substances Act and accompanying regulations. Such conduct was a result of Rite Aid's lack of robust policies and procedures regarding dispensing controlled substances as well as Rite Aid's focus on profitability over its legal obligations and public safety.

317. Rite Aid's dispensing policies and procedures used at all its Rite Aid pharmacies nationally were deficient in many ways. A few examples are illustrative.

318. Rite Aid implemented a policy for dispensing "high-alert" controlled substances for the first time in 2013. The policy was a simple checklist consisting of six steps: 1) Receive the prescription; 2) Validate the Prescription; 3) Validate the Prescriber: 4) Validate the Patient; 5) Decide to dispense or not to dispense; and 6) Report any suspicious activity. Yet Rite Aid provided little to no guidance on how to perform the vague tasks and the policy was little more than words on a page. In another example, Rite Aid only started to alert its pharmacists of patients' attempts to get early refills – a red flag of diversion – in 2016.

319. Rite Aid also did nothing to ensure that even its pro forma policies were being followed. Rite Aid did not audit its pharmacies for compliance with its own controlled substances dispensing policies or compliance with the CSA's requirements regarding legal dispensing.

320. As a sophisticated, national chain pharmacy, Rite Aid had the ability to analyze data relating to drug utilization and prescribing patterns across multiple retail stores in diverse geographic locations. Its own data would have allowed Rite Aid to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper or illegitimate prescribing.[53]

321. Yet, Rite Aid only started tracking "High Alert data" in September, 2015 at the corporate level. Even then, it did not use the data to effectively comply with its legal obligations to prevent diverison and ensure only legal prescriptions were being filled at its pharmacies. For example, Rite Aid provided its pharmacists no visibitlity into the data it collected, thereby depriving them of an invaluable resource when evaluating prescriptions.

[53] *See, e.g.*, *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,315 (Dep't of Justice Oct. 12, 2012) (decision and order) (DEA expert witness examined dispensing records alone to identify inappropriately dispensed medications).

322. In contrast to its lack of robust policies to ensure only prescriptions issued for a legitimate medical purpose were dispensed, Rite Aid had numerous and detailed policies regarding metrics to ensure its profitability. These policies ensured that Rite Aid pharmacists did not have the time, resources, or support to adequately discharge not only their legal duties as pharmacists, but also their alleged duties under Rite Aid's own policies and procedures.

323. For example, in 2011, Rite Aid adopted a policy whereby it promised to fill prescriptions in 15 minutes or less.[54] If a prescription took more than 15 minutes to fill, the patient would get a $5 gift card. Rite Aid touted the program as something consumers wanted, but many others recognized the danger such a program was to patients and the practice of pharmacy. Numerous State Boards of Pharmacy objected to the program. As the chair of the Illinois State Board of Pharmacy said: "This is 180 degrees away from everything we are trying to do in moving the pharmacy profession toward being patient information-focused rather than product-focused. And it's counter to our many efforts to improve patient safety."

324. Despite eventually doing away with the 15 minute or less promise, Rite Aid continued to carefully track its pharmacists' prescription fill speeds, thereby ensuring that the pharmacists were not able to exercise their corresponding responsibility under the law. In fact, Rite Aid pharmacies routinely filled prescriptions at a pace of multiple prescriptions per minute.

325. Rite Aid's compensation policies also blocked pharmacists from preventing illegitimate prescriptions from being dispensed. Rite Aid's compensation policies provided bonuses that depended on the number of prescriptions—including opioids—dispensed from Rite Aid pharmacies. Even when Rite Aid eventually, ostensibly removed controlled substances from

[54] Drug Topics, *Rite Aid offers 15-minute Rx guarantee*, May 15, 2011, https://www.drugtopics.com/chains-business/rite-aid-offers-15-minute-rx-guarantee.

its bonus calculations, Rite Aid continued to evaluate its pharmacies on their profitability. Indeed, pharmacists' jobs depended on the profitability of the pharmacy; if the pharmacy was not profitable enough staff would be laid off or it would be closed entirely. A pharmacy's profitability is heavily dependent on its prescription volume, including controlled substances. So even if removed from bonus calculations, the amount of prescriptions dispensed by a pharmacy and corresponding effect on a pharmacy's bottom line still acted as a powerful incentive for pharmacies to focus on dispensing *all* prescriptions, instead of only legal ones. Rite Aid did nothing to counter this perverse incentive and, in fact, encouraged profit over patients.

326. The problem of illegal dispensing caused by Rite Aid's focus on quickly filling prescriptions and increasing the number of prescriptions dispensed was also exacerbated by Rite Aid's inadequate pharmacy staffing. Often, single pharmacists were left as the only pharmacist at a location for entire shifts. This greatly cut into the ability of the pharmacist to evaluate each prescription carefully and in accordance with the law.[55]

327. Rite Aid also evaluated its pharmacies on customer service. Perversely though, Rite Aid considered its pharmacist's refusal to fill a prescription as a "service failure," despite their pharmacist's legal obligation to refuse to fill certain prescriptions.

328. The effect of Rite Aid's actions was all too predictable and tragic. Through five pharmacies in the County, Rite Aid purchased more than ***9.6 million*** dosage units of oxycodone

[55] Some states have tried to outlaw pharmacists from working alone. California, for example, passed a law saying no pharmacist could be required to work alone. Regrettably, however, it has been largely ignored since taking effect last year, according to leaders of a pharmacists' union. *See* Gabler, Ellen, *How Chaos at Chain Pharmacies is Putting Patients at Risk*, THE NEW YORK TIMES (Jan. 31, 2020), https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html.

and hydrocodone at five stores in Lake County from 2006 to 2014, the years for which ARCOS data is available.

e. Rite Aid Failed to Maintain Effective Controls Against Diversion and Instead Fueled a Black Market in the County.

329. As a vertically integrated distributor and dispenser of prescription opioids, Rite Aid knew or should have known that an excessive volume of pills was being sold into Ohio and the County.

330. The sheer volume of prescription opioids distributed to and dispensed by Rite Aid pharmacies in and around the County is indicative of potential diversion and required appropriate due diligence.

331. Further, analysis of ARCOS data also reveals that a single Painesville Rite Aid bought over 4.2 million dosage units of oxycodone and hydrocodone from 2006-2014, which was enough for approximately 24 pills per year for each of the 19,524 people who live in the city—notwithstanding the fact that there was also a Walgreens and CVS located less than a half a mile away that flooded the same area with over 2.2 million and 1.6 million dosage units of oxycodone and hydrocodone, respectively, during the same time period, as well as at least seven additional pharmacies within a five-mile radius of these high-buying Rite Aid location. Painesville is included among the two areas of the County in which a 2018 article reported overdoses were particularly concentrated.

332. Discovery will reveal that Rite Aid knew or should have known that its pharmacies in Ohio, and the surrounding area, including West Virginia, Michigan, and Kentucky, were (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from

out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash; (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription "cocktails"; (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets. Rite Aid had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

333. Because of its vertically integrated structure, Rite Aid has access to complete information regarding red flags of diversion across its pharmacies in and around the County, but Rite Aid failed to utilize this information to effectively prevent diversion.

iv. Walmart

a. Walmart Failed to Maintain Effective Controls Against Diversion.

334. Walmart is the largest private employer in the United States by far. It employs more than 1.5 million people. But for years, Walmart chose not to assign a single employee to design or operate a system to detect suspicious orders of controlled substances. Walmart chose to do nothing while hundreds of thousands of people were dying, and waited until 2014 to begin to take meaningful action. By that time, it was too late.

Walmart Lacked a Suspicious Order Monitoring System for Most of the Relevant Time Period.

335. Like other Defendants, Walmart self-distributed opioids to its retail stores. Specifically, Walmart operated registered distribution centers to supply its own pharmacies with controlled substances from the early 2000s until 2018 when it ceased self-distributing controlled substances. Walmart's conduct is particularly troubling given that it acted both as a self-distributing and dispensing pharmacy for such a long period of time.

336. Prior to 2011, Walmart had not designed any formal system to identify suspicious orders of controlled substances and, therefore, utterly failed to meet its statutory obligations.

337. Walmart has claimed that its hourly employees and associates—who were also responsible for filling orders at Walmart Distribution Centers—monitored the orders they were filling for unusual size, pattern, and frequency. Typically, this "review" involved between 700 and 800 orders a day. Walmart has also claimed that these hourly associates were instructed to alert a supervisor if an order appeared unusual based on their experience and memory.

338. Upon information and belief, Walmart can produce no written evidence of any such instructions to Walmart associates, no evidence of any training that would be required to implement such a procedure, or anyone actually being alerted about an unusual order or performing any follow up inquiry.

339. Walmart failed to provide any guidance to the associates as to what constitutes a "suspicious" order. Instead, Walmart emphasized its associates' subjective judgment based on their "knowledge and experience" as distribution center employees. There is no evidence that any Walmart employee ever flagged an order as suspicious prior to 2011.

340. Walmart purportedly implemented a "monitoring program" that would identify suspicious orders of controlled substances in 2011. This system purportedly was in place until 2015.

341. Walmart's monitoring program was insufficient to identify suspicious orders of controlled substances. The program flagged only very large orders of controlled substances. Specifically, it flagged weekly orders for controlled substances of 50 bottles (5,000 dosage units) or more and orders or more than 20 bottles (2,000 dosage units) that were 30% higher than a rolling four-week average for that item. Orders under 2,000 units per week were never flagged, meaning that a pharmacy could order 8,000 units per month without ever being flagged. Moreover, that meant that even if an order was more than 30% greater than the four-week average, it could not draw an alert unless it also was more than 20 bottles.

342. Under this system, an alert did not mean Walmart would report the order or halt it pending necessary due diligence. To the contrary, upon information and belief, Walmart *never* reported an order flagged by its monitoring program to the DEA as suspicious. In addition, rather than halting the order, Walmart simply cut the order to the amount of the 50 bottles threshold and shipped it. Walmart never reported cut orders to the DEA. Although information regarding flagged orders was available and sent daily to Walmart's headquarters in Arkansas (the "Home Office"), no one from the Home Office ever reviewed or took *any action* regarding flagged orders.

343. This practice continued until mid-2012, when Walmart implemented "hard limits" on opioid orders. Under this approach, weekly orders of Oxycodone 30mg ("Oxy 30") were automatically reduced to 20 bottles. Still, Walmart failed to report the orders to the DEA.

344. During this time period, Walmart also monitored weekly orders of other controlled substances in quantities of more than 20 bottles. Specifically, an "Over 20 Report" was provided to the Home Office in the morning and if nothing was done by mid-afternoon, the orders were filled and shipped. Upon information and belief, there is no evidence of any order in fact being held or reviewed pursuant to this practice.

345. Further, cutting the order did not mean that the Walmart pharmacy would not receive the full supply. Walmart pharmacies also purchased opioids from outside suppliers, including McKesson and AmerisourceBergen. Pharmacies could place another order with these outside vendors to make up the difference, or in some cases, have orders fulfilled by both Walmart and a third-party distributor at the same time. Thus, even though Walmart had the ability to monitor such orders, it chose not to, which allowed its pharmacies to surpass its already high thresholds by simply ordering drugs from a third party.

346. Walmart knew that its monitoring program was insufficient to fulfill its obligations to prevent diversion. For example, in 2013, Walmart acknowledged in an internal presentation that it had not yet designed a compliant system for suspicious order identification, monitoring, and reporting. It also stated that it was "TBD" when Walmart would develop such a system. In June 2014, Walmart again acknowledged that it lacked a compliant monitoring program. Moreover, Walmart acknowledged in 2014 that it had "no process in place" to comply with government regulations and that this created the "severe" risk of "financial or reputational impact to the company."

347. It was not until late 2014 that Walmart's written policies and procedures required orders of interest to be held and investigated.

1. Walmart's "Enhanced" Monitoring Program Fails to Remedy Deficiencies in its Monitoring Program.

348. In 2015, Walmart enhanced its suspicious order monitoring policy by implementing store-specific thresholds. Upon information and belief, it based these thresholds on the standard deviation of a specific pharmacy's order history for each controlled substance. The thresholds also included minimum amounts, below which no orders were flagged under any circumstance, regardless of pattern or frequency.

349. Walmart's corporate designee, testifying on its behalf in the MDL, conceded that thresholds were set for business purposes, not for the purpose of "main[taining] of effective controls against diversion . . . into other than legitimate . . . channels . . . ." 21 U.S.C.A. § 823(a)(1), (b)(1). Further, for almost all Walmart pharmacies, this minimum was set at 2,000 dosage units per week (or 8,000 dosage units per month). Accordingly, even when Walmart implemented a store specific policy that took into consideration a pharmacy's order history, the program was still woefully deficient because it did not account for changes in ordering patterns. A pharmacy could, for example, go from ordering 10 dosage units of Oxycodone 10 mg per month to 7,999 per month without any order being flagged or reviewed.

350. With respect to Walmart's suspicious order monitoring system for its wholesale distribution, the MDL Court has denied a motion for summary judgment contesting the evidence regarding the inadequacy of Walmart's suspicious order monitoring efforts in that litigation. *See* Opinion and Order Denying Walmart's Motion for Summary Judgment, MDL No. 2804, Doc. 3102 (N.D. Ohio Jan. 27, 2020). In doing so, it "noted[d] the record evidence suggests obvious deficiencies that a layperson could plainly recognize." *Id*. at 4 n. 12.

b. Walmart Failed to Guard Against Diversion in Distributing into Lake County.

351. According to data from the ARCOS database, between 2006 and 2014, Walmart distributed more than ***6.7 million*** dosage units of oxycodone and hydrocodone to Walmart pharmacies in Lake County. The volume of opioids Walmart shipped into the County—and then sold from its Walmart pharmacy locations in the County—was so high as to raise a red flag that not all of the prescriptions being ordered could be for legitimate medical uses.

352. Yet, upon information and belief, Walmart did not report a single suspicious order in the County between 2007 and 2014**.** Instead, Walmart funneled far more opioids into Ohio and

the County than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. This information, along with the information known only to distributors such as Walmart (especially with its pharmacy dispensing data), would have alerted Walmart to potential diversion of opioids.

353. In addition, Walmart, upon information and belief, also distributed and dispensed substantial quantities of prescription opioids in other states, and these drugs were diverted from these other states to Ohio. Walmart failed to take meaningful action to stop this diversion despite its knowledge of it, and it contributed substantially to the opioid epidemic in Ohio.

354. In the County, Walmart violated the standard of care for a distributor by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities it knew or should have known could not be justified and signaled potential diversion.

355. For years, per capita opioid prescriptions in Ohio far exceeded the national average and increased in ways that should have alerted Walmart to potential diversion. Indeed, as a vertically integrated, national retail pharmacy chain, Walmart had the ability to detect diversion in ways third-party wholesale distributors could not by examining the dispensing data from their own retail pharmacy locations.

356. Given the volume and pattern of opioids distributed in Ohio and in the County, Walmart was, or should have been aware that opioids were being oversupplied into the state and should have detected, reported, and rejected suspicious orders. Yet, the information available shows it did not.

357. Upon information and belief, Walmart by virtue of the data available to it, was actually aware of indicia of diversion, such as (1) individuals traveling long distances to fill

prescriptions; (2) prescriptions for drug "cocktails" known for their abuse potential, such as oxycodone and Xanax; (3) individuals who arrived together with identical or nearly identical prescriptions; (4) high percentage of cash purchases; and (5) doctors prescribing outside the scope of their usual practice or geographic area. However, Walmart ignored these obvious red flags.

358. Walmart therefore, was aware of the suspicious orders that flowed from its distribution facilities. Walmart refused to identify, investigate, and report suspicious orders despite its actual knowledge of drug diversion. Rather, Walmart failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids flowing into Ohio and the County.

359. Upon information and belief, Walmart failed to analyze: (a) the number of opioid prescriptions filled by its pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; and (c) the number of opioid prescriptions filled relative to other drugs.

360. Walmart was, or should have been, fully aware that the opioids being distributed and dispensed by it were likely to be diverted; yet, it did not take meaningful action to investigate or to ensure that it was complying with its duties and obligations with regard to controlled substances, including its responsibility to report suspicious orders and not to ship such orders unless and until due diligence allayed the suspicion.

361. Given Walmart's retail pharmacy operations, in addition to its role as a wholesale distributor, Walmart knew or reasonably should have known about the disproportionate flow of opioids into Ohio and the County and the operation of "pill mills" generating opioid prescriptions that, by their quantity or nature, were red flags for, if not direct evidence of, illicit supply and diversion.

c. Walmart Failed to Maintain Effective Controls Against Diversion from its Lake County Pharmacies.

362. Walmart, throughout the relevant time period, owned and operated pharmacies throughout the United States, including pharmacies in the County. Through its wholly owned or controlled subsidiary companies, Walmart operates over 4,500 retail pharmacies across the U.S., a mail-order pharmacy, a specialty pharmacy, and six pharmacy distribution centers that distribute to other Walmart entities.

363. Walmart set policies for its pharmacies at the corporate level. Walmart also presented, through nationwide advertising, a public image of the safety and excellence of all the pharmacists the company hired. In a recruitment video for pharmacists on Walmart's YouTube channel, the company shows Walmart pharmacists speaking about working at the company: "the safety and the excellence we carry to our patients is phenomenal," adding that "the culture that our company has [is] respect for the individual, service, and excellence, and, of course, we always have integrity."[56] The commercial also states that Walmart's pharmacists "strive for excellence" and are "passionate about providing quality healthcare."

364. Walmart pharmacies in and around Lake County received distributions of prescriptions from Walmart's distribution centers and from other wholesale distributors, which enabled these pharmacies to have the same orders filled by both Walmart and a third-party distributor.

365. The volume of prescription opioids dispensed by Walmart pharmacies in and around the County is indicative of potential diversion and required appropriate due diligence.

[56] Walmart, *Your Career as a Walmart Pharmacist* (Sept. 25, 2014), available at https://www.youtube.com/watch?v=9VD12JXOzfs (last visited May 13, 2020).

366. Through three pharmacies in the County, Walmart purchased more than ***6.4 million*** dosage units of oxycodone and hydrocodone from 2006 to 2014, the years for which ARCOS data is available.

367. One Walmart store, located at 33752 Vine St in Willowick, alone bought over 3.2 million dosage units of oxycodone and hydrocodone from 2006-2014, which was enough for approximately 25 pills per year for each of the 14,175 people who live in the city, even though there were at least nine other pharmacies within a five-mile radius of this Walmart location.

368. As a vertically integrated distributor and dispenser of prescription opioids, Walmart had unique insight into all distribution and dispensing level data, and knew or should have known that it was dispensing an excessive volume of pills into Ohio and around the County.

369. Discovery will reveal that Walmart knew or should have known that its pharmacies in Ohio, and the surrounding area, including West Virginia, Michigan, and Kentucky, were: (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash; (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines or prescription "cocktails"; (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of

opioids in similarly sized pharmacy markets. Walmart had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

370. Walmart had complete access to all prescription opioid distribution data related to Walmart pharmacies in and around Lake County.

371. Walmart had complete access to all prescription opioid dispensing data related to Walmart pharmacies in and around Lake County.

372. Walmart had complete access to information revealing the doctors who prescribed the opioids dispensed in Walmart pharmacies in and around Lake County.

373. Walmart had complete access to information revealing the customers who filled or sought to fill prescriptions for opioids in Walmart pharmacies in and around Lake County.

374. Walmart had complete access to information revealing the opioids prescriptions dispensed by Walmart pharmacies in and around Lake County.

375. Walmart had complete access to information revealing the geographic location of out-of-state doctors whose prescriptions for opioids were being filled by Walmart pharmacies in and around Lake County.

376. Walmart had complete access to information revealing the size and frequency of prescriptions written by specific doctors across Walmart pharmacies in and around Lake County.

377. Yet, Walmart failed to put in place effective policies and procedures for the dispensing of prescription opioids, and failed to provide adequate guidance to its pharmacists on dispensing opioids. Moreover, Walmart's pressure on pharmacists to fill more prescriptions quickly was at odds with a culture and practice of compliance. Incentive awards were tied to the number of prescriptions a pharmacy filled and profit that the pharmacy generated. Upon

information and belief, controlled substances were included in Walmart's pharmacy incentive program for most of the relevant time period. In addition, pharmacists were under constant pressure to increase the number of prescriptions they filled, and to increase the overall percentage of pharmacy sales. As a result, upon information and belief, because of Walmart's drive for speed, pharmacists often did not have enough time to sufficiently review a prescription and conduct the appropriate due diligence.

378. Even when Walmart pharmacists suspected diversion based on an individual prescriber's prescribing practices, for years, Walmart did not allow its pharmacists to request blanket refusals to fill. Walmart, however, had always had the ability to do so. Finally, in 2017, Walmart implemented a policy by which individual pharmacists could request such blanket refusals, which would permit the pharmacist to refuse to fill future prescriptions from that prescriber without evaluating each prescription individually. In addition, Walmart also always had the ability to "centrally block" problematic prescribers across all Walmart and Sam's Club pharmacies, but did not establish a procedure to do so until 2017. In the "Practice Compliance" document describing this policy, Walmart admitted that it may, "in certain situations," have information about prescribing practices that is not available to individual pharmacists:

> While pharmacists are in the best position to determine whether individual prescriptions are appropriate, *additional information may be obtained that is not available to our pharmacists*. Therefore, in certain situations, a prescriber may be identified whose prescribing practices raise concerns about prescribing controlled substances for legitimate medical purposes. After a thorough review, these additional insights may lead Walmart to place a block in Connexus on controlled substance prescriptions from these prescribers.

379. Moreover, Walmart's policies and procedures often were at odds with the pressure for pharmacists to fill prescriptions quickly. Pharmacists were under constant pressure to increase the number of prescriptions they filled, and to increase the overall percentage of pharmacy sales.

As a result, upon information and belief, pharmacists often did not have enough time to sufficiently review a prescription and conduct the appropriate due diligence.

380. These systemic issues are reflected in numerous enforcement actions and investigations that demonstrate the Walmart put profits and sales ahead of compliance, its customers and communities, and public safety. In 2009, for example, the DEA issued a Show Cause order seeking to revoke the registration of a Walmart pharmacy in California. The order alleged that the pharmacy:

> (1) improperly dispensed controlled substances to individuals based on purported prescriptions issued by physicians who were not licensed to practice medicine in California; (2) dispensed controlled substances . . . based on Internet prescriptions issued by physicians for other than a legitimate medical purpose and/or outside the usual course of professional practice . . . ; and (3) dispensed controlled substances to individuals that [the pharmacy] knew or should have known were diverting the controlled substances.

381. In addition, a 2011 Memorandum of Agreement ("2011 MOA") arising out of the investigation states that the DEA also learned that the same pharmacy was allegedly dispensing controlled substances based on prescriptions that lacked valid DEA numbers and allegedly refilling controlled-substances prescriptions too early.

382. Upon information and belief, the failures described in the 2011 MOA were not limited to California but reflected systemic failures at the corporate level. Indeed, the 2011 MOA, which required Walmart to maintain a "compliance program" states that it is applicable to "all current and future Walmart Pharmacy locations."

383. Following the 2011 MOA, Walmart was supposed to revamp its dispensing compliance program, but still, its policies and procedures remained deficient.

384. Instead, systemic failures continued, and Walmart's national corporate office not only failed to insist that Walmart implement adequate controls against diversion, they ignored concerns raised by Walmart pharmacists.

385. One internal document from 2015, for example, notes concerns from a Walmart pharmacist that "his leadership would not support his refusing to fill any 'legitimate' (written by a Dr) prescriptions and he stated that his current volume/staffing structure doesn't allow time for individual evaluation of prescriptions[.]" When this pharmacist refused to fill a customer's controlled substance prescription because the customer was attempting to fill it too soon, the Market Health & Wellness Director for that store complained to management that the pharmacist "sent a customer to a competitor" and "expressed significant concern about how 'sending customers away' would impact the sales figures for the store," and insisted that "the store needs to fill every available prescription."

386. In October 2018, the U.S. Department of Justice ("DOJ") had evidence that Walmart pharmacies in Texas dispensed opioids that killed customers who overdosed on the drugs. "The pharmacists who dispensed those opioids had told the company they didn't want to fill the prescriptions because they were coming from doctors who were running pill mills," but their pleas "for help and guidance from Walmart's corporate office" fell on deaf ears.[57] Pharmacists in a number of other states also sought help from Walmart's corporate office, also to no avail. Walmart compliance officials failed to take action in response to these alarms. "Instead, they repeatedly admonished pharmacists that they could not cut off any doctor entirely."[58] Even if pharmacists believed the doctor was operating a pill mill, rather than providing genuine medical care, "[t]hey could only evaluate each prescription on an individual basis."[59] In fact, a 2011 document from

[57] Jesse Eisinger and James Bandler, *Walmart Was Almost Charged Criminally Over Opioids. Trump Appointees Killed the Indictment.*, ProPublica, (March 25, 2020), https://www.propublica.org/article/walmart-was-almost-charged-criminally-over-opioids-trump-appointees-killed-the-indictment

[58] *Id.*

[59] *Id.*

Walmart Regulatory Affairs regarding the "Proper Prescriber-Patient Relationship" stated, "Blanket refusals of prescriptions are not allowed. A pharmacist must make an individual assessment of each prescription and determine that it was not issued based on a valid prescriber-patient relationship or a valid medical reason before refusing to fill."

387. A Texas federal prosecutor, in connection with an investigation that began in 2016, described a systemic problem. The investigation showed Walmart's issue was not a few rogue employees. Rather, "Walmart had a national problem."[60] The investigation reportedly revealed that between 2011 and 2017, "Walmart pharmacists repeatedly filled prescriptions that they worried were not for legitimate medical purposes, including large doses of opioids and mixtures of drugs the DEA considered red flags for abuse.[61] They did so even though Walmart pharmacists in Texas, Maine, North Carolina, Massachusetts, Kansas and Washington all "raised alarms to the company's national compliance department about doctors."[62] Regarding one Texas doctor who was later convicted of illegal distribution of opioids, a Walmart pharmacist wrote; *"We are all concerned about our jobs and about filling for a pill mill doctor. . . Please help us."*[63] Another described the same doctor as a "problem," a "liability for us," and a "risk that keeps [him] up at night," cautioning "[t]his is a serious situation."[64] Similarly, in September 2016, a Walmart pharmacist in Pennsylvania advised that a doctor was "under investigation by the DEA for what we believe is a pill mill operation," and that Rite Aid had begun refusing to fill his prescriptions,

[60] *Id.*
[61] Jesse Eisinger and James Bandler, *Walmart Was Almost Charged Criminally Over Opioids. Trump Appointees Killed the Indictment.*, ProPublica, (March 25, 2020), https://www.propublica.org/article/walmart-was-almost-charged-criminally-over-opioids-trump-appointees-killed-the-indictment
[62] *Id.*
[63] *Id.*
[64] *Id.*

prompting prescriptions from this prescriber, which were "*almost solely narcotic and controlled prescriptions*" to double.[65] Still, Walmart adhered to its policy of requiring a case-by-case analysis of each prescription from the suspected pill mill placed with any Walmart pharmacy; it would not block the prescriber in its system or allow a "blanket" refusal to fill. Walmart was more concerned with the potential sale than it was with preventing diversion.

388. Upon information and belief, Walmart also failed to adequately use data available to it to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts or doses of opioids, or to adequately use data available to it to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

389. Upon information and belief, Walmart also failed to conduct adequately analyze and address its opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if it conducted such reviews, it failed to take any meaningful action as a result.

Giant Eagle

a. Giant Eagle Failed to Maintain Effective Controls Against Diversion.

390. Although Giant Eagle had access to significant information about red flags due to its vertical integration with its stores, both failed to use available information from indicating red flags in order to more effectively prevent diversion.

1. For All But Two Months, Giant Eagle Lacked A SOM System, and It Failed to Follow the Policy It Did Have.

391. For nearly the entire five-year period that it distributed hydrocodone combination products ("HCP")s, Giant Eagle had no written suspicious order monitoring (SOM) policy.

[65] *Id.*

Rather, by Giant Eagle's own admission, its earliest written SOM policy is dated August 1, 2014. Giant Eagle stopped distributing controlled substances at issue in October 2014. HBC, then, operated as a distributor of controlled substances without a written SOM policy for all but two (2) months of its time distributing controlled substances.

392. Giant Eagle 's August 2014 written SOM policy consisted of four short bullet points which were part of a larger policy. This policy relied on Giant Eagle, Inc.'s corporate office to alert HBC if Giant Eagle pharmacies engaged in suspicious ordering. The policy also directed that HBC would prepare and communicate any history of suspicious orders to the "GE" Pharmacy team "as requested," not making such a report a matter of course. The policy then required GE Pharmacy team, *not HBC*, to notify the DEA "with in [sic] the prescribed three day time limit." In this way, Giant Eagle's actual policy was to delegate its DEA reporting responsibility to its customers' owner.

393. Further, HBC's August 1, 2014 policy does not identify how its SOM system operated, but rather outlines the process for reporting suspicious product orders. The policy does not elaborate on how to identify a suspicious order, nor does HBC's warehouse supervisor recall any specific training to identify suspicious orders. HBC has also admitted in written discovery responses in this MDL that it provided no "educational, information and/or other programs to any Customer and/or pharmacy/dispenser that it owns and/or controls or other Person, that address diversion, safety, efficacy, misuse and/or prescription of Schedule II Opioids."

394. Giant Eagle's attempt to identify orders of unusual size also was deeply flawed. On October 15, 2013, after approximately four (4) years of distributing HCPs, Giant Eagle finally began to aggregate its customers' controlled substance orders and apply a rudimentary threshold to identify suspicious ordering behavior. From that point until it stopped distributing HCPs, HBC

produced a daily spreadsheet that identified shipments, each of which had already been shipped to the pharmacy, that exceeded the chain-wide ordering threshold for the particular drug. HBC admitted that the threshold report kept track of the shipped quantities, not the ordered quantities, further emphasizing the lack of pre-shipping due diligence.

395. The thresholds themselves were also deficient. HBC set thresholds for controlled substances by taking the average amount *all* of its customers ordered and multiplying by three (3). The effect is that when a customer whose orders for a controlled substance in a month exceeded 300% of the average HBC customer, it was flagged on HBC's threshold report. As HBC since has admitted, setting thresholds by a chain-wide average can result in both false positives (large-volume store consistently orders more than threshold) and false negatives (small-volume stores' relatively large order does not exceed chain-wide threshold).

396. Giant Eagle also repeatedly misrepresented existence of a written SOM policy, its use of algorithms to flag customers' suspicious orders, and its ability to review and stop suspicious orders before shipping to its customers. It even lied to DEA agents when directly asked whether it had HCPs in its warehouse (shortly before hydrocodone's rescheduling after which HBC's registration, which extended only to Schedule III drugs, would expire. More recently, however, HBC's 30(b)(6) representative admitted that it did not have the ability to review and stop suspicious orders before shipping during the entire time HBC distributed opioids.

b. Giant Eagle Failed to Maintain Effective Controls Against Diversion in the County at the Wholesale Level.

397. In the County, Giant Eagle violated the standard of care for a distributor by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities it knew or should have known could not be justified and signaled potential diversion.

398. Giant Eagle distributed more than ***3.5 million*** dosage units, of oxycodone and hydrocodone from 2006 to 2014 to pharmacies in the County, the years for which ARCOS data is available. The volume of opioids it shipped into, and dispensed from locations in, the County is so high as to raise a red flag that not all of the prescriptions being ordered could be for legitimate medical uses.

399. Giant Eagle funneled far more opioids into Ohio and the County than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. This information, along with the information known only to distributors such as Giant Eagle especially with its pharmacy dispensing data), would have alerted Giant Eagle to potential diversion of opioids. Yet, upon information and belief, Giant Eagle did not report a single suspicious order in the County between 2007 and 2014.

400. Upon information and belief, Giant Eagle by virtue of the data available to it, was actually aware of indicia of diversion, such as (1) individuals traveling long distances to fill prescriptions; (2) prescriptions for drug "cocktails" known for their abuse potential, such as oxycodone and Xanax; (3) individuals who arrived together with identical or nearly identical prescriptions; (4) high percentage of cash purchases; and (5) doctors prescribing outside the scope of their usual practice or geographic area. However, Giant Eagle ignored these obvious red flags.

401. Giant Eagle, therefore, was aware of the suspicious orders that flowed from its distribution facilities. Giant Eagle refused to identify, investigate, and report suspicious orders despite its actual knowledge of drug diversion. Rather, Giant Eagle failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids flowing into Ohio and the County.

402. Upon information and belief, Giant Eagle failed to analyze: (a) the number of opioid prescriptions filled by its pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; and (c) the number of opioid prescriptions filled relative to other drugs.

403. Giant Eagle was, or should have been, fully aware that the opioids being distributed and dispensed by it were likely to be diverted; yet, it did not take meaningful action to investigate or to ensure that it was complying with its duties and obligations with regard to controlled substances, including its responsibility to report suspicious orders and not to ship such orders unless and until due diligence allayed the suspicion.

404. Given Giant Eagle's retail pharmacy operations, in addition to its role as a wholesale distributor, Giant Eagle knew or reasonably should have known about the disproportionate flow of opioids into Ohio and the County and the operation of "pill mills" that generated opioid prescriptions that, by their quantity or nature, were red flags for, if not direct evidence of, illicit supply and diversion.

c. Giant Eagle Failed to Maintain Effective Controls Against Diversion from Its Pharmacy Stores.

405. HBC representatives have admitted that Giant Eagle pharmacy staff have diverted prescription opioids, amounting to tens of thousands of units.

406. Red flags should also have been apparent given that the State of Ohio Board of Pharmacy found that Giant Eagle Pharmacy #4098, in Chardon, Ohio, "from May 1, 2009 through January 21, 2011, fail[ed] to provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs, to wit: the following controlled substances and dangerous drugs were stolen from the pharmacy yet internal control procedures failed to deter or detect the theft.":

Drug	**Strength**	**Shortage**	**Percent of Stock**
hydrocodone with APAP	5/325	1,321	53.92
hydrocodone with APAP	5/500	(-648)	0.65
hydrocodone with APAP	7.5/325	5,237	67.49
hydrocodone with APAP	7.5/500	6,161	72.06
hydrocodone with APAP	7.5/750	30,566	57.67
hydrocodone with APAP	10/325	5,282	75.67
hydrocodone with APAP	10/500	14,586	75.19
hydrocodone with APAP	10/650	5,523	82.07
hydrocodone with APAP	10/660	17,512	82.22
hydrocodone with ibuprofen	7.5/200	1,057	52.33
Carisoprodol	350	7,556	27.68
Suboxone	8	553	20.04[66]

The State Board further found that "[t]he drugs were stolen by an inadequately supervised technician who admitted to a Board agent that the drugs were diverted to her addicted husband and

[66] Table from Ohio Board of Pharmacy, Docket Number D-110714-197: *In the Matter of Giant Eagle Pharmacy #4098.*

also sold to another individual." These figures demonstrate Giant Eagle's knowledge of and failure to prevent diversion.

407. Additional unreported diversion from Giant Eagle pharmacies is evidenced in monthly narcotic audit reports and in the testimony of Giant Eagle Pharmacy District Leader Fred Bencivengo, who testified as to several instances in a single narcotic audit report where suspected diversions of opioids should have been but were not reported. Pharmacists and their supervisors also list "HBC Warehouse" as the cause of hundreds of missing opioids on these monthly narcotic audits.

408. Giant Eagle also conspired with McKesson to circumvent any meaningful limit on distribution to its pharmacies through McKesson's: (1) daily warnings about thresholds being approached; (2) omitting part of Giant Eagle's orders which would exceed a threshold without notifying DEA of the threshold-exceeding order; (3) and following McKesson's direction to submit to McKesson a request to increase thresholds for its pharmacies approaching or meeting set thresholds.

409. The sheer volume of prescription opioids distributed to and dispensed by Giant Eagle pharmacies in and around Lake County is indicative of potential diversion and required appropriate due diligence.

410. Discovery will reveal that Giant Eagle knew or should have known that its pharmacies in Ohio, and the surrounding area, including West Virginia, Michigan, and Kentucky, were (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in

cash; (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription "cocktails"; (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets. Giant Eagle had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

411. Through seven pharmacies in the County, Giant Eagle purchased more than ***10.7 million*** dosage units of oxycodone and hydrocodone from 2006 to 2014, the years for which ARCOS data is available.

412. Further, analysis of ARCOS data also reveals, for example, that, a single Giant Eagle pharmacy in the County purchased more than 2.6 million dosage units of oxycodone and hydrocodone from 2006 to 2014, which was enough for approximately 40 pills per year for each of the 7,436 people who live in the city of Mentor on the Lake – notwithstanding the fact that there was also a Walgreens located less than half a mile away that flooded the same area with over 2.3 million dosage units of oxycodone and hydrocodone from the same time period. On top of that, there were at least seven additional pharmacies within a five-mile radius of this store.

B. <u>Defendants' Performance Metrics Put Profits Before Safety.</u>

413. Not only did the Chain Pharmacies; lack (and fail to implement) adequate policies and procedures to guard against diversion, but CVS, Rite Aid, and Walgreens, and upon information and belief, the other Chain Pharmacies compounded this problem by implementing performance

metrics and prescription quotas for retail stores that contributed to supplying of a black market, including in the County.

414. In connection with the DEA's investigations described above, the DEA found evidence that Walgreens had a corporate policy encouraging increased sales of oxycodone.[67] As the DEA's September 2012 Order to Show Cause and Immediate Suspension of Registration explains:

> In July 2010, Walgreens's corporate headquarters conducted an analysis of oxycodone dispensing for the prior month at its Florida retail pharmacies and produced an 11 page spreadsheet, ranking all Florida stores by the number of oxycodone prescriptions dispensed in June. The spreadsheet was sent to Walgreens's market pharmacy supervisors in Florida on July 29, 2010, with the admonition that they "*look at stores on the bottom end .... We need to make sure we aren't turning legitimate scripts away. Please reinforce*." A corporate market director of pharmacy operations did reinforce this message to Florida market pharmacy supervisors, highlighting that their "*busiest store in Florida*" was filling almost 18 oxycodone prescriptions per day, yet "We also have stores doing about 1 a day. Are we turning away good customers?"

415. In 2011, a Walgreens project to "Increase Rx Sales and prescription Counts" instructed pharmacies to "improve C2 business" – i.e. dispense more Schedule 2 controlled substances. This focus on *increasing* controlled substance dispensing – including opioids – continued even after the DEA investigation and $80 million fine. For example, in 2014, the RX Integrity department created a "Pharmacist Controlled Substance Dispensing Opportunities" tool to "identify pharmacists that are dispensing a low rate of controlled substances," and help pharmacists "feel more comfortable in filling controlled substances," specifically focusing on pharmacists dispensing low rates of opioids like "hydromorphone, oxycodone, methadone… hydrocodone," and the cocktail drugs comprising the rest of the "holy trinity" of abuse, such as "carisoprodol… [and] alprazolam."

[67] WAGMDL00387654-666 (September 13, 2012 Order to Show Cause and Immediate Suspension of Registration to Walgreens's Jupiter, Florida Distribution Center).

416. Walgreens also had a bonus program that factored prescription volume into bonus calculations, and served as an incentive for pharmacies and pharmacy technicians to ignore the "red flags" of diversion. The corporate push for speed (or volume) deterred pharmacists from taking the time to properly examine the prescriptions before them and exercising their corresponding responsibility to prevent diversion.

417. Walgreens emphasized in its policies for pharmacist and pharmacy managers: "The best evidence of a well-run pharmacy is the increase in prescriptions and pharmacy sales." One former Walgreens pharmacist described management critiques for "not going fast enough" in dispensing prescriptions and believed "[t]hey'd like you to fill one a minute if you could." She recalled there was even a timer to alert her if she was falling behind, and threats of reduced hours or a move to a different store or location. Indeed, Walgreens had a tool, the "PhLOmometer" that tracked the time to fill a prescription. A March 2013 memo confirms that volume targets included controlled substances as late as 2013 and even after the adopting of the GFD policy. Specifically, the memo states, as the response to an "[a]nticipated question" that "GFD concerns doesn't relieve you from trying to attain the numbers that have been set for you." When considering high schedule 2 dispensing at a particular pharmacy in New Jersey in 2012, as the opiate crisis raged, the pharmacy supervisor pushed back against any attempt to reduce supply of oxycodone, focusing on the impact the reduction would make on filled prescriptions and "the bonus tied to" one pharmacy employee.

418. As described further below, pharmacists were expected to meet volume and speed goals. With respect to the volume-based bonus policy, a March 2013 memo confirms that volume targets included controlled substances as late as 2013 and even after the adopting of the GFD

policy. Specifically, the memo states, as the response to an "[a]nticipated question" that "GFD concerns doesn't relieve you from trying to attain the numbers that have been set for you."

419. Only as part of its 2013 settlement with the DEA, did Walgreens agree to exclude controlled substances calculations from bonus calculations from 2014 forward. This resulted in a 21% reduction in the number of stores purchasing the 80mg OxyContin – evidence that a minimal effort to implement common sense controls had a tangible impact on sales of the most potent controlled substances (although that reduction did not last, as described above, and Walgreens's volume by 2014 had increased again).

420. Walgreens also lobbied against imposition of caps or limits on the volume of prescriptions a pharmacist may fill. As the New York Times recently reported, pharmacists at chain pharmacies, including Walgreens have "said it had become difficult to perform their jobs safely, putting the public at risk of medication errors," as they "struggle to fill prescriptions, give flu shots, tend the drive-through, answer phones, work the register, counsel patients, and call doctors and insurance companies … all the while racing to meet corporate performance metrics that they characterized as unreasonable and unsafe …."[68] Instead of reducing performance targets, chain pharmacies including Walgreens seek to assign more dispensing tasks to less qualified – and less expensive – pharmacy technicians.

421. CVS used performance metrics related to its own profits, which would rely, in part, upon the number of prescriptions dispensed. By 2010, CVS had implemented performance metrics that remain publicly available online. CVS's metrics system lacked any measurement for pharmacy accuracy or customer safety. They did, however, prioritize speed and volume, including

[68] *See* Ellen Golbler, How Chaos at Chain Pharmacies is Putting Patients at Risk, New York Times, Jan. 31, 2020.

by requiring pharmacists to meet wait- or fill-time expectations. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacist fills within a year. Opioid prescriptions were even included in the volume goals until 2013, and after that time, the pressure from the metrics' focus on profitability remained. These policies remained in place even as the epidemic raged. Opioid prescriptions were even included in the volume goals until 2013, and after that time, the pressure from the metrics' focus on profitability remained. Even in 2020, pharmacists described CVS as the "most aggressive chain in imposing performance metrics."[69]

422. As noted above, former pharmacists at both Walgreens and CVS have publically complained about pressure to put speed ahead of safety. Concerning the metrics at CVS, one pharmacist commented that "You get stressed, and it takes your mind away from the actual prescriptions." Another former CVS pharmacist recalled that "[e]very prescription [wa]s timed," and a backlog would pop up in color on pharmacists computer screens if they fell behind.[70] Additionally, CVS has faced discrimination complaints alleging that the company's "Metrics" system set unobtainable goals — or at least, goals that could not be obtained without violating the laws and practice rules governing pharmacists' professional responsibilities, edging out older pharmacists.

[69] Ellen Gabler, *How Chaos at Pharmacies Is Putting Patients at Risk*, New York Times, (Jan. 31, 2020), https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html

[70] Sam Roe, Ray Long, and Karisa King, Contract Reporters, *Pharmacies Miss Half of Dangerous Drug Combinations*, Dec. 15, 2016, http://www.chicagotribune.com/news/watchdog/druginteractions/ct-drug-interactions-pharmacy-met-20161214-story.html

423. More recently, a former CVS pharmacist in North Carolina described being driven to leave his position and open his own pharmacy, where he could work safely. [71] He described working a 13-hour shift with no breaks for lunch or dinner at CVS the day before he left in December 2018; a day on which he filled "552 prescriptions — about one every minute and 25 seconds — while counseling patients, giving shots, making calls and staffing the drive-through."[72] In departing, he let his manager know that he would not "work in a situation that is unsafe."[73] One pharmacist was so alarmed that he wrote anonymously to the Texas State Board of Pharmacy to caution: "I am a danger to the public working for CVS."[74] It is difficult to contemplate how any pharmacist could and/or would be able to meaningfully comply with any corporate policy regarding red flag analyses or any anti-diversion analysis under such draconian pressures.

424. Walgreens and CVS were not alone in this regard. As described above, Rite Aid had performance metrics in place that exacerbated its failures. Without describing individual pharmacies, Daniel Hussar, a nationally-known expert and teacher of pharmacology at Philadelphia's University of the Sciences, commented in the media that the pace and pressure of prescription quotas appeared to be having an impact on accuracy. "The frequency of these errors is increasing greatly," Hussar said; "I've heard some pharmacists say, 'It's a blur as to what happened during the day and I can only pray I didn't make any serious mistakes.'"[75]

---

[71] Ellen Gabler, *How Chaos at Pharmacies Is Putting Patients at Risk*, New York Times, (Jan. 31, 2020), https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html
[72] *Id.*
[73] *Id.*
[74] *Id.*
[75] *Are Business Tactics at Some Pharmacies Risking Your Health?*, ReachMD citing ksdk.com (Nov. 8, 2017), https://reachmd.com/news/are-business-tactics-at-some-pharmacies-risking-your-health/1610793/.

425. This pressure and focus on profits would not only lead to mistakes, it also would necessarily deter pharmacists from carrying out their obligations to report and decline to fill suspicious prescriptions and to exercise due care in ascertaining whether a prescription is legitimate.

426. Indeed, "a survey by the Institute for Safe Medication Practices (ISMP) revealed that 83% of the pharmacists surveyed believed that distractions due to performance metrics or measured wait times contributed to dispensing errors, as well as that 49% felt specific time measurements were a significant contributing factor."[76]

427. In 2013, the National Association of Boards of Pharmacy (NABP), passed a resolution which cited this survey and additionally stated that "performance metrics, which measure the speed and efficiency of prescription work flow by such parameters as prescription wait times, percentage of prescriptions filled within a specified time period, number of prescriptions verified, and number of immunizations given per pharmacist shift, may distract pharmacists and impair professional judgment" and "the practice of applying performance metrics or quotas to pharmacists in the practice of pharmacy may cause distractions that could potentially decrease pharmacists' ability to perform drug utilization review, interact with patients, and maintain attention to detail, which could ultimately lead to unsafe conditions in the pharmacy."[77]

428. Still, according to a 2016 investigation by the *Chicago Tribune*, as chain pharmacies increasingly promote quick service, "pharmacists frequently race through legally required drug safety reviews — or skip them altogether," missing dangerous drug combinations in

[76] NAPB, Performance Metrics and Quotas in the Practice of Pharmacy (Resolution 109-7-13) (June 5, 2013), https://nabp.pharmacy/performance-metrics-and-quotas-in-the-practice-of-pharmacy-resolution-109-7-13/.

[77] *Id.*

the process.[78] A pharmacist too rushed to check for a potentially deadly drug interaction is also likely to be too rushed to check for red flags of diversion, such as prescription "cocktails" or other combinations of highly abused drugs.

429. According to the *Tribune's* coverage, "Wal-Mart, operator of 4,500 U.S. pharmacies, failed 43 percent of its tests."[79] Walgreens, meanwhile, failed a test of whether pharmacists would dispense dangerous drug combinations without warning patients 30 percent of the time.[80] Further, a Walmart pharmacist commented that she typically filled 200 prescriptions in her daily nine-hour shift, and an even higher volume when working at a different store, equating to two prescriptions per minute.[81]

430. In reporting on the results of its investigation, the *Tribune* quoted Bob Stout, president of the New Hampshire Board of Pharmacy, stating that "'They're cutting corners where they think they can cut."[82] As the report itself explained: "some pharmacies emphasize fast service over patient safety. Several chain pharmacists, in interviews, described assembly-line conditions in which staff hurried to fill hundreds of prescriptions a day.[83]

431. More recently, a January 2020 *New York Times* article, referenced above, revealed that the problematic performance metrics remain, and have remained, in place. One South Carolina pharmacist advised:

---

[78] Sam Roe, Ray Long, and Karisa King, Contract Reporters, *Pharmacies Miss Half of Dangerous Drug Combinations*, Dec. 15, 2016, http://www.chicagotribune.com/news/watchdog/druginteractions/ct-drug-interactions-pharmacy-met-20161214-story.html.

[79] *Id.*

[80] *Id.*

[81] *Id.*

[82] *Id.*

[83] *Id.*

> We are being asked to do things that we know at a gut level are dangerous. If we won't or can't do them, our employers will find someone else who will, and they will likely try to pay them less for the same work.

432. In March 2020, journalists also revealed that Walmart not only ignored reports of suspicious activity from pharmacists concerned that they were filling prescriptions for pill mills, but the company considered these pharmacists' focus misdirected. One internal email, reviewed by ProPublica, showed that in response to a question from a regional manager in 2015 about documenting pharmacists' concerns about doctors believed to be operating pill mills, Walmart's director of Health and Wellness Practice Compliance, Brad Nelson, wrote that "We have not invested a great amount of effort in doing analysis on the data since the agreement [requiring such reporting] is virtually over. *Driving sales and patient awareness is a far better use of our Market Directors and Market manager's time*.[84]

433. As described above, Walmart refused to allow pharmacies to flag and block all prescriptions from doctors whose prescriptions raised red flags that they were running pill mills. Not only did pharmacists have to refuse each prescription individually, to do so, "a pharmacist had to fill out a form that could take 20 minutes, a bureaucratic hurdle that pharmacists sought to avoid because they were under pressure to fill prescriptions quickly. [85]

C. Defendants Worked Together to Increase Their Profits and Lobbied Against Restrictions on Opioid Use and DEA Enforcement.

434. The DEA's suspensions of the registrations of three major distributors in 2007, lit a fuse within the industry. The very real threat of DEA enforcement prompted a flurry of communications between NACDS members and members of the HDA, described above, as well

[84] Jesse Eisinger and James Bandler, *Walmart Was Almost Charged Criminally Over Opioids. Trump Appointees Killed the Indictment.*, ProPublica, (March 25, 2020), https://www.propublica.org/article/walmart-was-almost-charged-criminally-over-opioids-trump-appointees-killed-the-indictment

[85] *Id.*

as the now-notorious Pain Care Forum ("PCF"), a forum run by opioid manufacturers. A goal of HDA, which it shared with NACDS, was to "develop a comprehensive DEA strategy" to avoid enforcement actions against distributors.

435. The NACDS and Defendants' other trade groups saw their role in influencing diversion policy as being one that was absolutely critical, considering all that was at stake. At times, these groups adopted militaristic strategies and used terminology ironically similar to the "War on Drugs," developing "task forces" and viewing the DEA's crackdown on distributors and chain pharmacies as an assault on the companies themselves. Only this time, the war was being waged against the very regulatory authorities and government entities fighting to deal with the ever-growing problem of abuse and diversion in this country.

> To follow up from last week's Pain Care Forum meeting, NACDS is interested in organizing a Task Force to respond to efforts to reschedule combination hydrocodone products into Schedule II. At a minimum, NACDS would like to organize to prepare for the October FDA hearing on this topic, but also would like to be prepared for any additional legislation that may be considered.
>
> NACDS has scheduled a conference call to organize the Task Force on July 26 at 10:30 a.m. The conference call number is: 888-450-5996, pass code: 608936#. Please email Kevin Nicholson at knicholson@nacds.org if you are interested in joining the Task Force but have a conflict for that time.
>
> Kevin N. Nicholson, R.Ph., J.D.
> Government Affairs and Public Policy
> National Association of Chain Drug Stores
> Tel: 703-837-4183

Manufacturers' participation in Defendants' trade groups as a means to effectuate favorable policies is clear when evaluated in the context of how Defendants and other stakeholders viewed the DEA's attempts to curb the opioid epidemic.

I wanted to say hello and I'm sorry that DEA is being so aggressive with this Suspicious Orders stuff.

I heard about your Lakeland, Florida distribution center effective next Monday. They're not going after your Jackson, MS distribution center, are they?

I wish there was something I could do to help in this situation - we are all in the same boat.

Best regards,

Jack

Jack Crowley
Executive Director
CSA Compliance
Purdue Pharma L.P.
One Stamford Forum
Stamford, CT 06901
203-588-8613 (w)
203-273-2656 (c)

436. Walgreens and the other Defendants, recognized the importance of controlling and influencing trade groups such as the NACDS in the context of influencing policy related to opioid drug abuse and diversion. The efforts taken by the NACDS and other trade groups on behalf of Defendants were so important to their bottom line that Defendants spared no expense in supporting such groups. Walgreens took a particularly aggressive view of this mutually beneficial relationship, at times, being its top donor across the country.

437. NACDS worked with the HDA, the Alliance to Prevent the Abuse of Medicines ("APAM"), and the PCF to support the Marino Blackburn Bill, also known as S.483 or the "Marino Bill. NACDS, and Defendants intended the Marino Bill to "tie the hands" of the DEA to actively and aggressively address diversion and compliance with the CSA." NACDS worked together with others in opioid supply chain to influence the language in the bill to make it most favorable for them and more restrictive on the DEA. Notably, masking the influence of industry, when the APAM was asked to sign on to a 2014 letter of support it was "signed by the Alliance, ***not the individual members***." The final letter that was sent to Senators Hatch and Whitehouse was signed

by the members of the Pain Care Forum as well as the Alliance, the NACDS, American Academy of Pain Management, and U.S. Pain Foundation.

438. The Marino Bill effectively removed the DEA's ability to issue immediate suspension orders regarding manufacturer or distributor registrations. The Marino Bill permitted a non-compliant registrant an opportunity to cure its noncompliance before the DEA could take enforcement action and changed the standard upon which revocation occurred. In the midst of a growing opioid crisis, the Marino Bill removed the most effective deterrent and constrained DEA enforcement actions.

439. With respect to its efforts to tie the hands of the DEA in its ability to pursue and hold accountable Defendants and other stakeholders for violations of law related to the sale and distribution of prescription opioids, CVS appreciated NACDS's influence.

From: Schlaifer, Marissa C </O=CVSCAREMARK/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=MARISSAC.SCHLAIFER>
To: Kevin Nicholson
CC: Eric Juhl; Gibbons, Thomas J.; Burton, Larry
Sent: 10/28/2013 8:27:06 AM
Subject: RE: No Policy Council Call this Week - Additional Items and Materials

Kevin –

Good work on the changes to the Marino bill. After reviewing the revised bill, our attorneys identified that it would still require drug testing/background checks of distribution center employees. So, we'd still prefer that it be limited to new employees only.

Thanks for your work on this!
Marissa

440. CVS as a member of the HDA, NACDS and the APAM was actively involved in efforts to curb the enforcement power of the DEA in its support of the Marino Bill. Its history and ties to the HDA and NACDS run deep.

441. The APAM is a trade group launched in the fall of 2013 and compromised of members of the American Medical Association, Cardinal, CVS, HDMA, Prime Therapeutics and Teva Pharmaceuticals.

442. CVS and Defendants used trade groups like the HDA, NACDS and APAM to gain favorable results when it came to regulations and roadblocks that were seen as being in the way of the Defendants ability to capitalize on the opioid business. In particular CVS would often hide behind the APAM when it knew its position could be controversial as it related to abuse and diversion. This particular letter was one in support of the controversial Marino Bill, a bill that CVS fought hard to push through, supporting it on three different fronts.

From: Schlaifer, Marissa C </O=CVSCAREMARK/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=MARISSA.SCHLAIFER>
To: Jenkins, Ann
Sent: 7/15/2014 5:16:24 PM
Subject: RE: Alliance: HR 4709 Sign On Letter to Speaker Boehner - Deadline tomorrow at 3p

Back to your question about whether the Alliance has signed rather than individual members:
It looks like they are proposing this because it's signing on to a group letter. If it's a letter from the Alliance, it's always signed by the individual members.

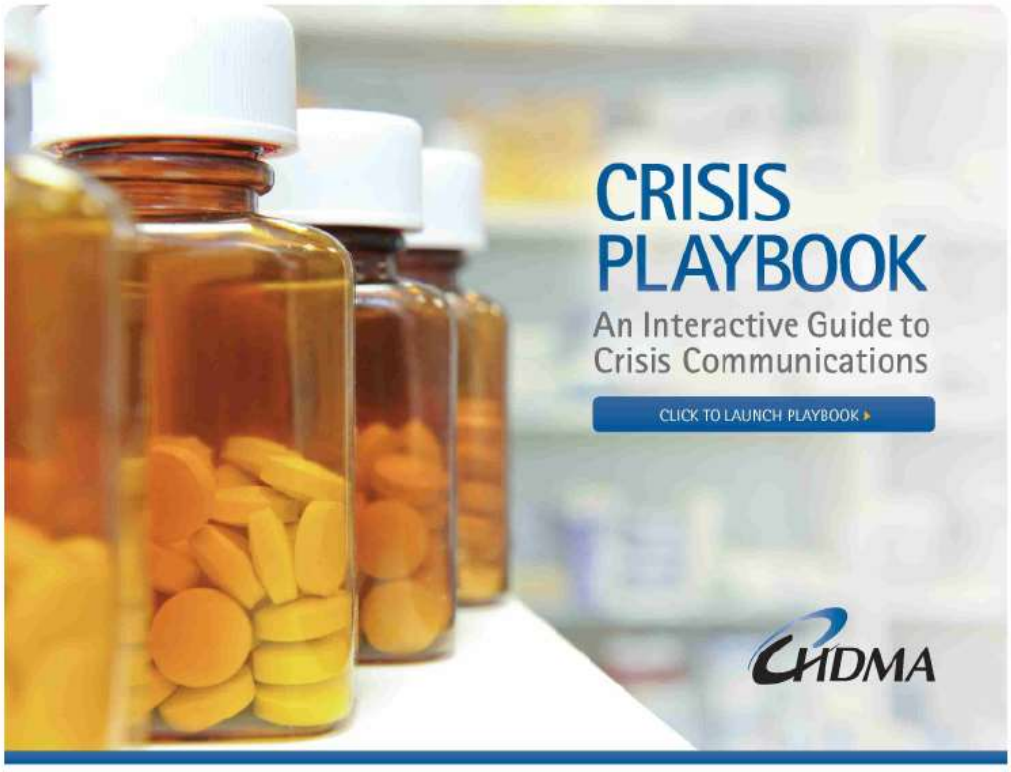
This might work for us since our name won't be on it ... but that's your call.

Marissa Schlaifer, R.Ph. I CVS Caremark I Head of Policy I 1300 I Street, N.W., Suite 525 West, Washington, DC 20005 I 202-772-3538 I marissa.schlaifer@cvscaremark.com

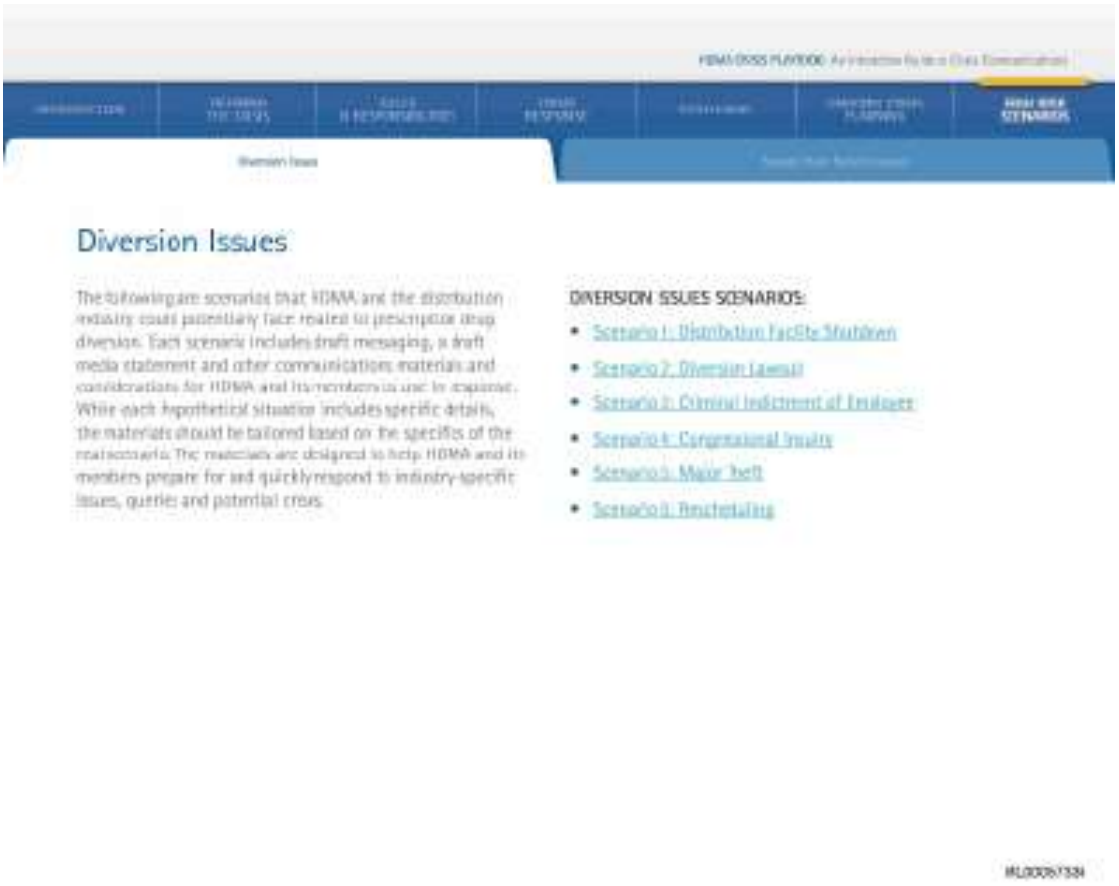
443. In August of 2011, NACDS worked with others on a joint letter opposing DEA fee increases for registrants that were intended to fund the "hir[ing of] more agents and do[ing] more inspections."

444. HDA's Crisis Handbook, developed in 2013, was a direct response to the "threats" perceived by HDA's members and affiliates, including Defendants, to their bottom line: profits derived from the distribution and sale of prescription opioids.[86] Defendants, did and continue, to rely on and employ the strategies discussed in the Crisis Playbook. Curiously, there are no slides on how best HDA and its members, including Defendants, might work to curb the crisis that is the opioid epidemic.

[86] ABDCMDL00278063.


CRISIS
PLAYBOOK
An Interactive Guide to
Crisis Communications
CLICK TO LAUNCH PLAYBOOK
CHDMA

ML00057311



445. In 2016, the NACDS Policy Council discussed ongoing efforts to shape opioid legislation, including their success in removing a requirement that pharmacists have to check their state drug monitoring program before filling controlled prescriptions.[87] NACDS also fought regulatory efforts to require Defendants to use available dispensing related data and red flags to prevent diversion, opposing what it described as "recent DEA actions in which DEA is expecting pharmacists to be enforcement agents with respect to prescriptions for pain medications.

446. NACDS and HDA sought to slow down and impede DEA enforcement activities by requiring the DEA to "work with the [Food and Drug Administration] FDA on all drug diversion issues," ostensibly on the grounds that the DEA's diversion enforcement activities – including "clos[ing] drug distribution centers and pharmacies" and "actions against pharmacies" were harmful

[87] WAGMDL00605718 (including Walgreens & Walmart).

in ""leading to patients not being able to receive their medications." This purported concern, however, was industry code for impediments to sales.

447. NACDS and HDA agreed that the pharmacies should "be more aggressive" and "lead the charge" with respect to certain DEA issues. NACDS members coordinated regarding pharmacy diversion and "DEA red flags" through a "DEA Compliance Workgroup." Defendants further used a NACDS "Pharmacy Compliance Roundtable" to discuss avoiding criminal and civil liability for issues related to controlled substances, SOM, and diversion. And, in May 2012, the NACDS formed a Policy Council "Task Group" to "discuss issues and develop strategies" concerning "ongoing problems that NACDS members are having with DEA enforcement actions," through which it sought to influence the government and media, set meetings with legislators seeking to "address the problems with DEA actions," and "collaborate with, and support others' efforts" including HDA.

D. Defendants Also Entered into Joint Ventures that Further Undermined their Outside Vendors Incentive to Conduct Due Diligence, While Increasing their Own Access to Information.

448. The collaboration between Defendants and other industry partners extended beyond their mutual interest in limiting regulations and enforcement that constrained their ability to sell opioids. Indeed, the companies had direct financial relationships that, quite literally, invested them in each others' success.

449. As described above, Walgreens entered into an exclusive arrangement with AmerisourceBergen as its supplier, with Walgreens obtaining both equity in AmerisourceBergen and a seat on its Board. As part of a three-year extension of that arrangement, in 2016, two agreed to include a requirement that AmerisourceBergen "make certain working capital investments in the relationship and will proceed with additional capital investments in its distribution network."

450. The merger between Walgreens and AmerisourceBergen had begun in 2012, when the two formed Walgreens Boots Alliance Development, a joint venture based in Switzerland. AmerisourceBergen was described as being able to gain from Walgreens's "purchasing synergies," through the companies' relationship.

451. In 2014, CVS entered into a 50/50 joint venture with Cardinal to create Red Oak Sourcing, LLC ("Red Oak"). Red Oak uses the combined generic purchasing power of CVS and Cardinal to negotiate with generic drug manufacturers, and its website touts its management of a "multi billion dollar pharmaceutical portfolio." To fund the venture, Cardinal would make quarterly payments of *$25.6 million* to CVS, and also would contribute additional funds if the joint venture reached certain milestones.

452. In 2016, McKesson and Walmart formed ClarusOne Sourcing Services LLP to source generic pharmaceuticals for their respective U.S. operations. As part of this "partnership," McKesson and Walmart "established an organization in London to provide strategic sourcing services for both companies," according to a job posting on McKesson's website.

453. Given that Walgreens, CVS, Walmart, on the one hand, the largest wholesalers, on the other, considered themselves partners invested in one another's success, they had even less incentive to turn away from the blind deference the Chain Pharmacies received when buying and selling controlled substances.

E. Defendants Worked With Opioid Manufacturers to Promote Opioids and Bolster Their Profits at the Expense of Communities Like the County.

454. Defendants also worked in concert with opioid manufacturers to ensure that the false messaging surrounding the treatment of pain and the true addictive nature of opioids was consistent and geared to increase profits for all stakeholders.

455. For example, as early as 2001, CVS worked closely with Purdue and its un-branded marketing arm, Partner's Against Pain ("PAP") to "fight back" against allegations (later proved to be true) that Purdue's Oxycontin was being abused at alarming rates. It was Purdue's Partner's Against Pain website that Purdue, and it's "Partners" including CVS, utilized to make the claims that the risk of addiction associated with Oxycontin was very small.

PURDUE

Stephen L. Seid
Sr. Director, National Accounts and Trade Relations
(203) 588-7315

TO: Jim Lang **FROM:** Steve Seid

RE: **CVS Pharmacy** **DATE:** May 11, 2001

Jim, on May 2, 2001 Don Tasser and I met with three of the key pharmacy people at CVS. They were:

- Barry Jasilli, R.Ph., J.D., Director, Quality Improvement
- Susan DelMonico, R.Ph., J.D., Director, Regulatory Compliance
- Sharon Galzarano, R.Ph., Manager of Professional Practices

The goal of the meeting was to talk about mutually beneficial initiatives with CVS to improve education with their pharmacists. We also wanted to reiterate our position on ensuring availability of OxyContin® for appropriate patients. I think overall the entire meeting was very productive and the CVS people were extremely supportive.

Key issues discussed were as follow:

1 They were resolute in their commitment to good pharmacy practice. Part of that good pharmacy practice is ensuring availability of OxyContin for appropriate patients. Their goal is good patient care.

2 As a group they were vocal, particularly Barry Jasilli, indicating that they felt that Purdue was in many ways being victimized by the situation. That the product is not the issue, but that the abuser is the issue. He indicated that, from his perspective, we should be fighting back even harder. We should be pointing out the benefits of our brand.

3 CVS will be sending out a copy of our Abuse and Diversion Brochure to 4,100 pharmacies. Our letter will be personalized for the CVS pharmacist and cosigned by Barry Jasilli and Susan DelMonico. They will also be sending out a version of the Abuse and Diversion Brochure with their logo.

4 CVS will also put a copy of the Abuse and Diversion Brochure on their intranet site called RxNet.

5 They will be looking to utilize both of our written CE Programs, in particular, for new grads coming to work for CVS.

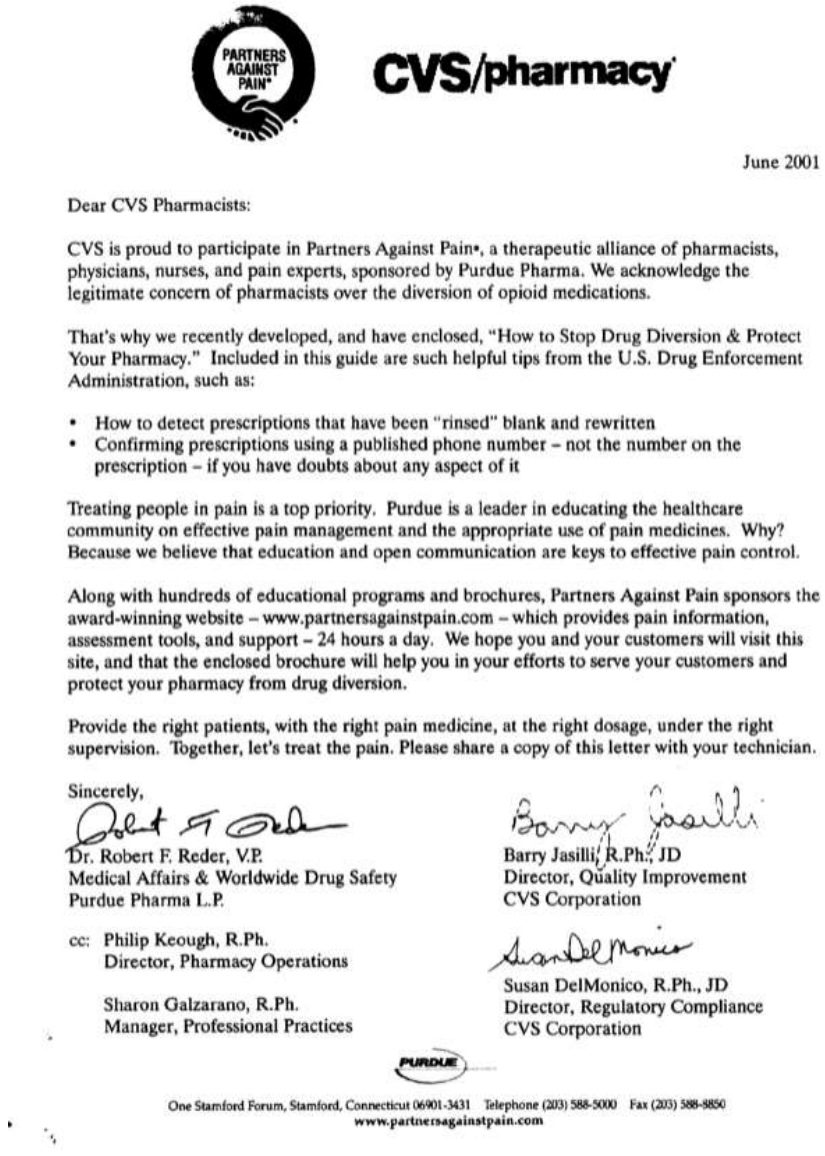
6 They talked about being more preemptive with our joint educational efforts. We will be setting up at least five programs at this time through CVS.

7 They talked about the possibility of co hosting programs in areas of healthcare professionals. I don't know if there was a unanimous agreement among the CVS people, but we will follow up to see if that is possible. Susan DelMonico will be the point person for CE Programs.

I believe we are garnering some significant support with CVS. Don Tasser will ensure follow up on these key programs.

456. Purdue worked together with CVS to ensure that CVS's own pharmacists were trained by Purdue on many of the misleading marketing messages that would later form the basis for a 2007 criminal guilty plea and $600 million fine between Purdue the Department of Justice

for misleading regulators, doctors, and patients about Oxycontin's risk of addiction and its potential for abuse. CVS's ties to PAP were so deep that CVS even went so far as to put CVS's own logo communications from its "partner".



PARTNERS AGAINST PAIN®

CVS/pharmacy

June 2001

Dear CVS Pharmacists:

CVS is proud to participate in Partners Against Pain®, a therapeutic alliance of pharmacists, physicians, nurses, and pain experts, sponsored by Purdue Pharma. We acknowledge the legitimate concern of pharmacists over the diversion of opioid medications.

That's why we recently developed, and have enclosed, "How to Stop Drug Diversion & Protect Your Pharmacy." Included in this guide are such helpful tips from the U.S. Drug Enforcement Administration, such as:

- How to detect prescriptions that have been "rinsed" blank and rewritten
- Confirming prescriptions using a published phone number – not the number on the prescription – if you have doubts about any aspect of it

Treating people in pain is a top priority. Purdue is a leader in educating the healthcare community on effective pain management and the appropriate use of pain medicines. Why? Because we believe that education and open communication are keys to effective pain control.

Along with hundreds of educational programs and brochures, Partners Against Pain sponsors the award-winning website – www.partnersagainstpain.com – which provides pain information, assessment tools, and support – 24 hours a day. We hope you and your customers will visit this site, and that the enclosed brochure will help you in your efforts to serve your customers and protect your pharmacy from drug diversion.

Provide the right patients, with the right pain medicine, at the right dosage, under the right supervision. Together, let's treat the pain. Please share a copy of this letter with your technician.

Sincerely,

Dr. Robert F. Reder, V.P.
Medical Affairs & Worldwide Drug Safety
Purdue Pharma L.P.

Barry Jasilli, R.Ph., JD
Director, Quality Improvement
CVS Corporation

cc: Philip Keough, R.Ph.
Director, Pharmacy Operations

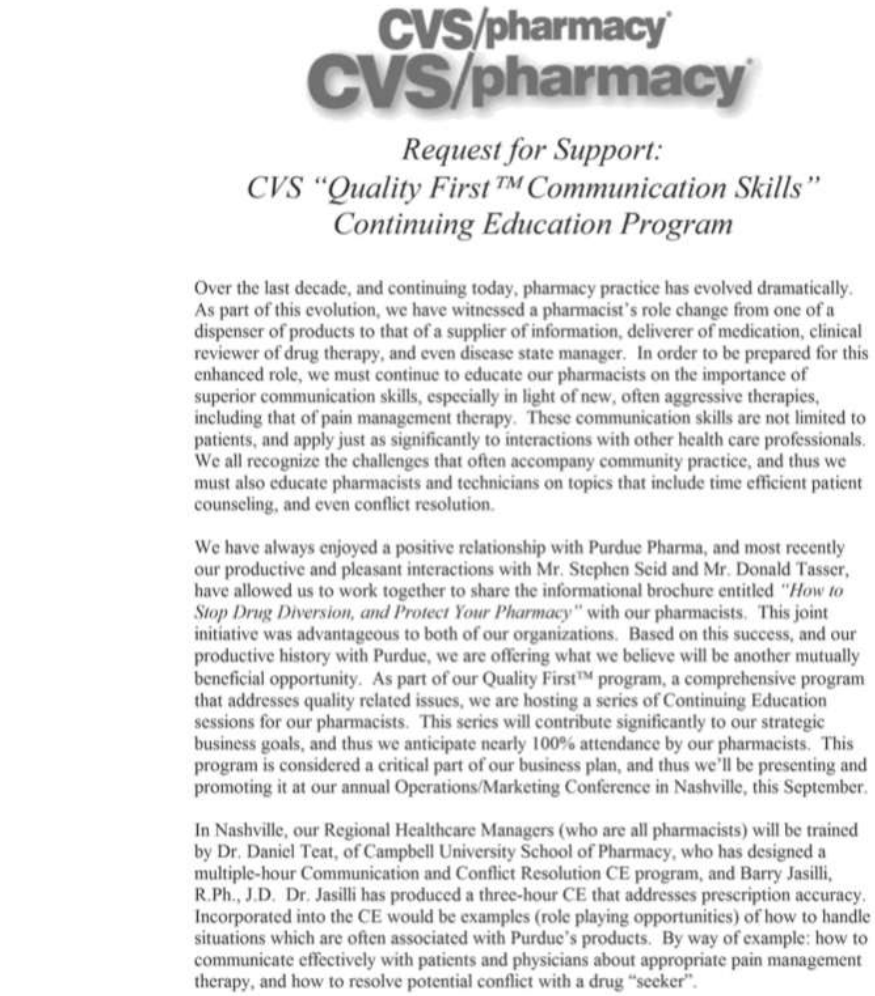
Sharon Galzarano, R.Ph.
Manager, Professional Practices

Susan DelMonico, R.Ph., JD
Director, Regulatory Compliance
CVS Corporation

PURDUE

One Stamford Forum, Stamford, Connecticut 06901-3431 Telephone (203) 588-5000 Fax (203) 588-8850
www.partnersagainstpain.com

457. CVS was so eager to ally itself with Purdue and its that it solicited Purdue for its participation in co-hosting Continuing Education programs for healthcare providers and pharmacists regarding training on diversion of prescription opioids.



CVS/pharmacy

CVS/pharmacy

Request for Support:
CVS "Quality First™ Communication Skills"
Continuing Education Program

Over the last decade, and continuing today, pharmacy practice has evolved dramatically. As part of this evolution, we have witnessed a pharmacist's role change from one of a dispenser of products to that of a supplier of information, deliverer of medication, clinical reviewer of drug therapy, and even disease state manager. In order to be prepared for this enhanced role, we must continue to educate our pharmacists on the importance of superior communication skills, especially in light of new, often aggressive therapies, including that of pain management therapy. These communication skills are not limited to patients, and apply just as significantly to interactions with other health care professionals. We all recognize the challenges that often accompany community practice, and thus we must also educate pharmacists and technicians on topics that include time efficient patient counseling, and even conflict resolution.

We have always enjoyed a positive relationship with Purdue Pharma, and most recently our productive and pleasant interactions with Mr. Stephen Seid and Mr. Donald Tasser, have allowed us to work together to share the informational brochure entitled *"How to Stop Drug Diversion, and Protect Your Pharmacy"* with our pharmacists. This joint initiative was advantageous to both of our organizations. Based on this success, and our productive history with Purdue, we are offering what we believe will be another mutually beneficial opportunity. As part of our Quality First™ program, a comprehensive program that addresses quality related issues, we are hosting a series of Continuing Education sessions for our pharmacists. This series will contribute significantly to our strategic business goals, and thus we anticipate nearly 100% attendance by our pharmacists. This program is considered a critical part of our business plan, and thus we'll be presenting and promoting it at our annual Operations/Marketing Conference in Nashville, this September.

In Nashville, our Regional Healthcare Managers (who are all pharmacists) will be trained by Dr. Daniel Teat, of Campbell University School of Pharmacy, who has designed a multiple-hour Communication and Conflict Resolution CE program, and Barry Jasilli, R.Ph., J.D. Dr. Jasilli has produced a three-hour CE that addresses prescription accuracy. Incorporated into the CE would be examples (role playing opportunities) of how to handle situations which are often associated with Purdue's products. By way of example: how to communicate effectively with patients and physicians about appropriate pain management therapy, and how to resolve potential conflict with a drug "seeker".

458. One would have to seriously question the accuracy of any training CVS pharmacists received from Purdue and Partners Against Pain on abuse and diversion, yet there has been no evidence provided by Defendants that CVS undertook any measures to re-educate its pharmacists on how or why Purdue and PAP training might be lacking in the area of diversion and abuse of opioids.

459. CVS's role was not limited to expanding the market for prescription opioids. CVS worked hard to ensure that demand for prescription opioids was not only sustained but multiplied.

It did so through its marketing, advertising and promotional efforts both on its own and in concert with other stakeholders.

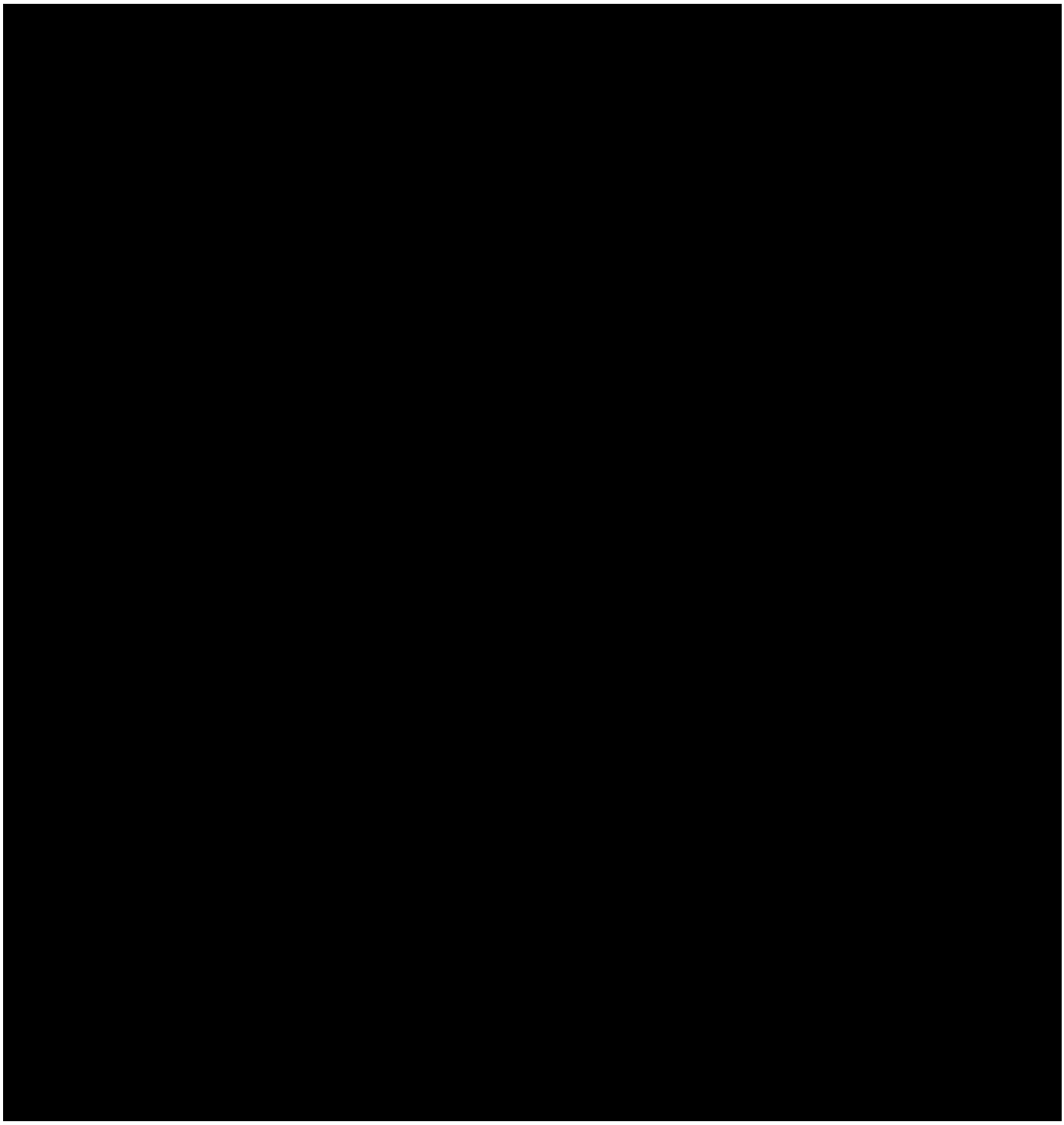
460. Contrary to what CVS has stated under oath in written discovery before this Court, CVS helped to grow the demand for prescription opioids and contributed to the public nuisance by participating in the marketing, advertising and promotion of opioid products with and on behalf of the opioid manufacturers.[88]

> **INTERROGATORY NO. 20:** State whether You have ever had any involvement, role or relation, directly or indirectly, financial or otherwise, with the marketing, advertising and/or promotion of any Opioid or Opioid Products conducted and/or directed by any manufacturer of Opioids or Opioid Products, from 1990 to the present. If so, state the manufacturer, the date or dates of any such advertising, marketing and/or promotion and the nature of Your involvement.
>
> Subject to and without waiving these objections, the CVS Distributors did not market Schedule II Opioids during the Subject Period.

461. CVS's marketing and promotion of opioids was not limited to its involvement with Purdue and Partners Against Pain. CVS did not draw lines when it came to promoting opioids, and there were no brand boundaries.

462. One example can be found in CVS's work with Endo Pharmaceutical ("Endo") to increase patient adherence to continuing their use of opioids. In fact, CVS played such an important part in the promotion of Endo's Opana ER, that it was included as having a crucial role in carrying out one of key sales tactics included in Endo's 2012 Business Plan.

[88] CVS Health's Objections and Responses to Plaintiffs' First Set of Interrogatories (6.18.2018), Rog Response #20.



463. Through a company called Catalina Health ("Catalina"), Endo was able to target Oxycontin patients in areas where Opana ER, a highly abused opioid manufactured by Endo, had preferred formulary status. Catalina in turn worked to create a brand loyalty program that kept new patients on their opioids. CVS, through its pharmacy retention programs, sent letters to the patients' homes to encourage them to stay on Opana – even though prolonged use of opioids

increases the risk of addiction, and even though patients in pain presumably need no reminder to continue to take their pain medications. CVS formalized its agreement to promote, market and advertise Endo's opioid products via its "CVS Carecheck Plus Patient Education Service"

Under this Agreement, CVS not only contractually agreed to promote Opana ER to its customers (patients) at the point of sale, but it even insisted upon reviewing and ***approving*** the specific messaging used.

464. Similarly, CVS contracted with manufacturers like Endo to ***prepare*** and disseminate materials promoting Opana ER nationwide.

465. CVS likewise helped Actavis promote its opioids by participating with Cardinal's Marketing and Business Development team in programs designed to offer rebates and off-invoice discounts on products, with the aim being to "move [] product."

Beneficial for both new and existing products, the *Rx*Deals offering is customized to meet your unique needs and is designed to provide special offers – rebates or off-invoice discounts – to retail chain and independent pharmacies, including CVS and Walgreen's, to help move your product.

Contact your Marketing and Business Development Sales Representative today and *Rx*Deal your way to maximizing your sales!

»View this week's ***Service Flash***

Thanks and have a great week!

The Marketing and Business Development Sales Team

Jeff Foreman, RPh
Vice President, Strategic Purchasing / Branded Purchasing
Office: 614.757.6674
jeff.foreman@cardinalhealth.com

466. Marketing, advertising and promoting opioids was not a new practice for CVS. In fact, CVS had been advertising these services to manufactures for years. For example, CVS made at least one pitch to Insys, a company whose senior executives were recently criminally convicted

for their unlawful marketing, to help sell its incredibly potent opioid, Subsys, a liquid form of fentanyl.

467. Here, CVS touted the reach of its communications and explained the science behind its sophisticated marketing, advertising and promotional services.

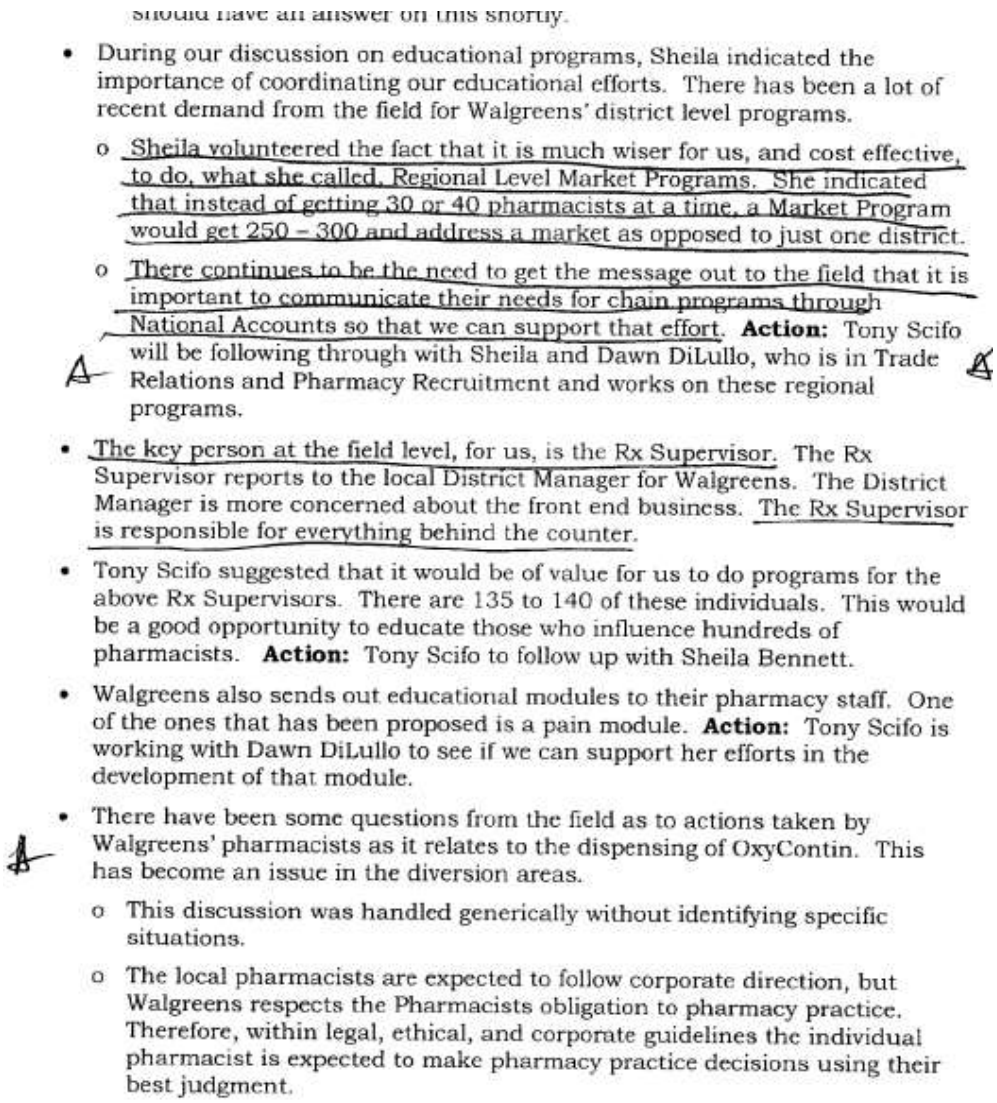
468. Hardly novices, CVS recognized its expertise in ensuring that opioid manufacturers like Insys were able to reach their intended market by using CVS's promotional programs which are designed to "deliver results."

469. Through CVS's NEWScript program, CVS claimed to be perfectly poised to assist with new product launches and described its truly impressive reach.

CVS even offered Insys the chance at having a literature display in its patient waiting rooms and to help Insys "target patients" using its signature ExtraCare consumer loyalty card database.

470. Working with Purdue as early as 2001, Walgreens played a pivotal role in expanding the market and ensuring the demand and supply for prescription opioids would grow to

exponentially. Purdue was particularly interested in using what Walgreens described to Purdue as its Regional Level Market Programs to educate pharmacists and patients on the benefits of Purdue's OxyContin.



should have an answer on this shortly.

- During our discussion on educational programs, Sheila indicated the importance of coordinating our educational efforts. There has been a lot of recent demand from the field for Walgreens' district level programs.
  - Sheila volunteered the fact that it is much wiser for us, and cost effective, to do, what she called, Regional Level Market Programs. She indicated that instead of getting 30 or 40 pharmacists at a time, a Market Program would get 250 – 300 and address a market as opposed to just one district.
  - There continues to be the need to get the message out to the field that it is important to communicate their needs for chain programs through National Accounts so that we can support that effort. **Action:** Tony Scifo will be following through with Sheila and Dawn DiLullo, who is in Trade Relations and Pharmacy Recruitment and works on these regional programs.
- The key person at the field level, for us, is the Rx Supervisor. The Rx Supervisor reports to the local District Manager for Walgreens. The District Manager is more concerned about the front end business. The Rx Supervisor is responsible for everything behind the counter.
- Tony Scifo suggested that it would be of value for us to do programs for the above Rx Supervisors. There are 135 to 140 of these individuals. This would be a good opportunity to educate those who influence hundreds of pharmacists. **Action:** Tony Scifo to follow up with Sheila Bennett.
- Walgreens also sends out educational modules to their pharmacy staff. One of the ones that has been proposed is a pain module. **Action:** Tony Scifo is working with Dawn DiLullo to see if we can support her efforts in the development of that module.
- There have been some questions from the field as to actions taken by Walgreens' pharmacists as it relates to the dispensing of OxyContin. This has become an issue in the diversion areas.
  - This discussion was handled generically without identifying specific situations.
  - The local pharmacists are expected to follow corporate direction, but Walgreens respects the Pharmacists obligation to pharmacy practice. Therefore, within legal, ethical, and corporate guidelines the individual pharmacist is expected to make pharmacy practice decisions using their best judgment.

In fact, Purdue leveraged its relationship with Walgreens and their mutually beneficial goal of growing the opioid business to ensure that Purdue had input into Walgreens "***corporate guidelines***" to which Walgreens pharmacists were "expected to follow" when it came to the dispensing of prescription opioids.

471. Walgreens also used its corporate oversight abilities to identify stores it believed were not filling enough oxycodone to make sure they weren't "turning away good customers" and encouraging stores to utilize continuing education created by opioid manufacturers to inform their decisions regarding dispensing.

472. Starting in at least 1999, Purdue sponsored Walgreens's Pharmacy continuing education programs designed to encourage stores to "get on the Pro Pain Management Band Wagon." Purdue was thrilled with the response and assistance it received from Walgreens when Purdue presented on "Pain Management for the Pharmacist." At the beginning of each Purdue sponsored meeting, a Walgreens pharmacist made a presentation on his store and the program implemented. His store actively advertised to area doctors and patients that they were a "full-service" pain management pharmacy. This service included providing a list to physicians' offices of all CIIs they had in stock (and they had everything), accepting "verbal orders" for Class II analgesics prior to presentation of the original prescription at the store to decrease "waiting time", allowing partial fills on CII prescriptions in terminal patients, and accepting after hours "emergency CII prescriptions" without a hassle. Purdue praised the pharmacist's actions as "fantastic".

473. Walgreens's use of pro-opioid continuing education continued as the opioids crisis grew. For example, Walgreens's Market Director of Pharmacy Operations recommended that Walgreens District Managers and Pharmacy Supervisors attend a continuing education program titled ""The Pharmacists' Role in Pain Management: A Legal Perspective," which was available on-line at RxSchool.com. This program was one in a long line of pharmacist "education" programs, or CEs, that opioid manufacturer Purdue developed as part of its strategy to disseminate "a new school of thought" about opioids. Through these programs, Purdue and the Chain

Pharmacies disseminated fraudulent information that redefined the red flags of abuse or diversion in an effort to correct pharmacists' "misunderstanding" about pain patients and the practice of pain management. Purdue took what it called an "aggressive role" in the education of Walgreens's and other pharmacists on pain management issues.

474. Walgreens's Market Director of Pharmacy Operations also recommended a second continuing education program titled "Navigating the Management of Chronic Pain: A Pharmacist's Guide."[89] The second "CE" incorporated into Walgreens's dispensing training program, "Navigating the Management of Chronic Pain: A Pharmacist's Guide" was sponsored by opioid manufacturer Endo Pharmaceuticals and disseminated manufacturer messaging designed to broaden the market for opioids. For example, it stated "according to most reports, approximately 30% of the population lives with chronic pain" and citing, *inter alia*, another CE presentation sponsored by the American Pain Society (another known front-group). It also claimed that "most opioid adverse effects can be managed with careful planning and patient education." It went on to discuss "fears and prejudices" related to addictive behaviors that "unnecessarily limit" opioid use, described as "opiophobia" which the piece claimed was the result of "misunderstandings regarding the concepts of addiction, physical dependence, and tolerance."

475. One of the presenters for this Endo sponsored CE was Kenneth C. Jackson. Mr. Jackson was a frequent speaker and Key Opinion Leader ("KOL") for Purdue. Mr. Jackson also co-authored the CE program titled "Use of Opioids in Chronic Noncancer Pain", which was sponsored by Purdue. Released in April 2000, it was designed to eliminate "misconceptions about addiction, tolerance and dependence" and contained many of the same messages as the pharmacist guide he authored.

[89] *Id*.

476. Walgreens also presented the video, The Pharmacist's Role in Pain Management - A Legal Perspective at mandatory meetings for pharmacy managers. This continuing education program ("CE") was also sponsored by Purdue, was similar to the earlier presentations, and was further disseminated to Walgreens pharmacists in June 2011. Released in 2009, the program was presented by Jennifer Bolen, JD. Ms. Bolen was a frequent speaker for Purdue and other opioid manufacturers, served as Special Counsel for the American Academy of Pain Medicine (a known front group for opioid manufactures), acted as a Key Opinion Leader ("KOL") for Purdue, and was described by Purdue as "a pain patient who takes opioids".

477. Armed with information gleaned from Purdue sponsored CE, the Walgreens pharmacists who had temporarily stopped filling controlled substances prescriptions began to accept them again. It is no surprise that in 2013 Walgreens acknowledged that several of the stores that touted this CE as part of their controlled substance action plan dispensed "certain controlled substances in a manner not fully consistent with its compliance obligations under the CSA."

478. Rite Aid likewise helped to expand the market and increase the demand for prescription opioids by working in concert with manufactures like Purdue. Capitalizing on Rite Aid's reach, Purdue worked with Rite Aid as early as 2001 to promote its highly addictive, OxyContin. The return on investment ("ROI") of such a program was clear to both Purdue and Rite Aid, as described below.

To: Stup, Sharlene
Cc: Geiwitz, Dr. Allen; Terifay, Terrence
Subject: Rite Aid Program

Sharlene:

I wanted to follow up regarding today's pharmacy program with Dr. Al Geiwitz at the Rite-Aid Corporate Office. Dr. Al addressed in great detail an overview of pain management, the JCAHO pain standards, and most importantly the abuse and diversion issues. Dr. Al's discussion was well received and greatly appreciated by all in attendance, especially John Boyle, Regional Pharmacy Development Manager.

Our ROI will best be defined by John, whose regional coverage extends to over 120 stores in Northeast Philadelphia, North Philadelphia, Mt. Airy, Bucks County, and other outreaches within our district. This is of great importance because prior to this program, John and many other pharmacists had concerns with regulatory issues surrounding purchasing quantities of OxyContin and identifying appropriate patients. Now, John has made himself available as an advocate and is willing to assist in our efforts in proper pain management education.

Sharlene, I am personally pleased with the efforts put forth by myself regarding this program. As you know, Rite-Aid has presented numerous challenges to the Philadelphia District in the past. I believe that by creating the need for proper education, I have the opportunity to make significant progress with the key Rite-Aid pharmacies in my territory.

Sincerely,
Heather

Both Purdue and Rite Aid recognized the importance of a chain pharmacy and pharmacists in the efforts to expand and sustain the demand for prescription opioids. Purdue memorialized its observation that as the last line of defense, ourpharmacists at the retail level" were the "most important audience. . . in highly sensitive areas" – presumably those already impacted, even in 2001, by the opioid epidemic.

-----Original Message-----
From: Lombardo, Ralph
Sent: Wednesday, April 18, 2001 10:29 PM
To: Cook, Dr. Mary; Geiwitz, Dr. Allen; Cramer, Phil
Cc: Richards, Tim; Gasdia, Russell; DaBronzo, Dr. Joseph
Subject: FW: Rite Aid Program

I want to thank Dr. Al, Dr. Mary Cook and Dr. Dabronzo for supporting our efforts in the Philadelphia area. This paid off. I received a voice mail today from Heather Peterson through Sharlene Stup informing us the Rite Aid DM asked her to be there today to do inservices for 25 more pharmacists and arranged for her to come back in the near future to address the rest of the pharmacists who were unable to attend. Our pharmacists at the retail level may be our most important audience right now, especially in the highly sensitive areas.

Thanks again

Ralph

F. Defendants Delayed a Response to the Opioid Crisis by Pretending to Cooperate with Law Enforcement

479. When a distributor does not report or stop suspicious orders, or a pharmacy fails to maintain effective policies and procedures to guard against diversion, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action—or may not know to take action at all.

480. Despite their conduct in flooding Ohio and other states with dangerous and unreasonable amounts of opioids, Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion.

481. In its 2011 MOA, Walgreens agreed to undertake several different anti-diversion measures. Yet, as a DEA official explained in a subsequent Order to Show Cause and Immediate Suspension of its registration that was issued a mere month later and pertained to Walgreens's

Jupiter Florida Distribution Center, Walgreens's "anti-diversion" measures appeared to be primarily self-serving:

> [W]hen a company undertakes to survey its stores for regulatory compliance, then selectively edits that survey for the explicit purpose of avoiding evidence of its own non-compliance, as Walgreens apparently did in May 2011, claims of effective remedial measures have less credibility. I gave significant weight to the fact that Walgreens appears to have deliberately structured certain of its antidiversion measures to avoid learning about and/or documenting evidence consistent with diversion. At best, I regard this as deliberate indifference on Walgreens'[s] part as to its obligations as a DEA registrant.
>
> My confidence in Walgreens'[s] remedial measures is lessened further by the fact that this manipulation of the compliance survey occurred just one month after Walgreens entered into a nationwide Memorandum of Agreement (MOA) with DEA to resolve an Order to Show Cause issued to a San Diego Walgreens pharmacy based on allegations of unlawful dispensing. . . . Walgreens'[s] effort to enact . . . [a compliance] program in Florida appears to have been, in part, intentionally skewed to avoid actually detecting certain evidence of possible diversion.

482. Despite the behavior described above, Walgreens nevertheless publicly portrayed itself as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion of these dangerous drugs.

483. In August of 2018, after journalists at the *Washington Post* disclosed information gleaned from the ARCOS data regarding the staggering number of opioids Walgreens distributed and sold, Walgreens again publicly promoted itself as being and "ha[ving] been an industry leader in combatting this crisis in the communities where our pharmacists live and work." Walgreens further asserted that "Walgreens pharmacists are highly trained professionals committed to dispensing legitimate prescriptions that meet the needs of our patients."[90]

[90] Aaron C. Davis & Jenn Abelson, *Distributors, pharmacies and manufacturers respond to previously unreleased DEA data about opioid sales*, Washington Post (Aug. 8, 2019), https://www.washingtonpost.com/investigations/distributors-pharmacies-and-manufacturers-respond-to-previously-unreleased-dea-data-about-opioid-sales/2019/07/16/7406d378-a7f6-11e9-86dd-d7f0e60391e9_story.html

484. Yet, in January 2020, Walgreens released a Board Report on Oversight of Risks Related to Opioids. There, it claimed that: "In recent years, the Company has implemented a number of operational changes that it believes have helped to reduce its risk with respect to its dispensing of prescription opioids. The Company is focused on the continuous improvement of its controlled substances compliance program, implementing enhancements to prevent, identify and mitigate the risk of non-compliance with federal and state legal requirements."[91] It went on to tout its "Good Faith Dispensing policy," as "provid[ing] the foundation for our pharmacists to understand their roles and responsibilities when dispensing prescriptions for controlled substances."[92] It also claimed that "the Company conducts its own voluntary, independent review of controlled substance purchase orders placed by our pharmacies, providing an additional layer of review above and beyond the legally required monitoring performed by the wholesalers."[93] There, Walgreens's Board acknowledged that the "fundamental elements of an effective compliance program include," among other things, "[w]ritten policies, procedures, and standards of conduct setting forth the Company's expectations and requirements for operating all business activities in an ethical and compliant manner"; "[o]versight of the Compliance Program by the Global Chief Compliance and Ethics Officer, Compliance and Ethics Officers for each operating division, and Compliance and Governance Committees"; and, "[a]uditing and monitoring."[94]

485. With respect to compensation, the Board stated: "[w]e have a strong pay-for-performance philosophy." Accordingly, its "Compensation and Leadership Performance

---

[91] https://s1.q4cdn.com/343380161/files/doc_downloads/governance_guidelines/Board-Report-on-Oversight-of-Risk-Related-to-Opioids-June-2019-rev.-August-2019.pdf
[92] *Id.*
[93] *Id.*
[94] *Id.*

Committee," the Board explained, "aims to incent leaders to support the Company's culture and model desired behaviors, ensuring ethical behavior and mitigating risks, through ongoing monitoring, reviewing and governance of all incentive plans."[95]

486. Yet, at the end of January 2020, the *New York Times* revealed that Walgreens had not reformed its policies putting speed ahead of safety and pharmacists continued to feel pressed to do more with less. According to the article, pharmacists at Walgreens and Rite Aid stores "described understaffed and chaotic workplaces where they said it had become difficult to perform their jobs safely, putting the public at risk of medication errors."[96] The article explained that these pharmacists "struggle to fill prescriptions, give flu shots, tend the drive-through, answer phones, work the register, counsel patients and call doctors and insurance companies," while "racing to meet corporate performance metrics that they characterized as unreasonable and unsafe in an industry squeezed to do more with less."[97]

487. Citing company documents, the article showed that Walgreens contuse to tie bonuses to achieving performance metrics. Walgreens, in response stated that errors were rare and that "it made 'clear to all pharmacists that they should never work beyond what they believe is advisable.'"[98] Similarly, CVS assured that "[w]hen a pharmacist has a legitimate concern about working conditions, we make every effort to address that concern in good faith."[99]

---

[95] *Id.*
[96] Ellen Gabler, *How Chaos at Pharmacies Is Putting Patients at Risk*, New York Times, (Jan. 31, 2020), https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html
[97] *Id.*
[98] *Id.*
[99] *Id.*

488. Meanwhile, the *New York Times'* coverage disclosed that a CVS form for staff members to report errors internally asked whether the patient poses "a 'media threat.'"[100] According to the article, "[t]he American Psychiatric Association is particularly concerned about CVS, America's eighth-largest company, which it says routinely ignores doctors' explicit instructions to dispense limited amounts of medication to mental health patients."[101] The group's president further observed that ""[c]learly it is financially in their best interest to dispense as many pills as they can get paid for[.]

489. Following its Texas settlement, Walmart claimed that the agreement pertained to a small number of stores in that state and claimed that Walmart was "eager to comply with the law."[102] A Walmart spokesperson further claimed that: "We take record keeping seriously[,]" and "[w]e continuously review our processes at our pharmacies to ensure they are accurate and in full compliance with the law."[103]

490. More recently, Walmart reportedly claimed to be cooperating with a federal investigation and "taking action to fix its opioid dispensing practices."[104] In fact, however, Walmart subsequently "acknowledged that it halted its cooperation in mid-2018."[105]

491. In August of 2019, after ARCOS data from the years 2006 to 2012 become public, a spokesman for Giant Eagle issued a public statement claiming that its "pharmacy Team

---

[100] *Id.*
[101] *Id.*
[102] Associated Press, *Wal-Mart Settles Drug Records Accusation*, (Jan 7, 2009), http://prev.dailyherald.com/story/?id=262762
[103] *Id.*
[104] Jesse Eisinger and James Bandler, *Walmart Was Almost Charged Criminally Over Opioids. Trump Appointees Killed the Indictment.*, ProPublica, (March 25, 2020), https://www.propublica.org/article/walmart-was-almost-charged-criminally-over-opioids-trump-appointees-killed-the-indictment
[105] *Id.*

Members are trained on a number of measures to ensure the legitimacy of prescriptions, to be mindful of red flags that may suggest prescription misuse, and to provide education and other support regarding proper medication adherence."[106] He went on tout the company's commitment to being part of the solution, not the problem, stating: "We recognize the severity of the opioid crisis affecting so many across our communities, and we are committed to doing our part to improve the health and well-being of those we serve."[107]

492. Rite Aid similarly claims to be committed to working with "both federal and state agencies to help reduce the opioid epidemic that is impacting our communities throughout the United States."[108]

251. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, all Defendants through the joint amicus brief filed by the HDA and NACDS in *Masters Pharmaceuticals*, described above, made the following statements:[109]

> a. "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."
>
> b. "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that is available to them in the ordering process."

493. Through the above statements made on their behalf by their trade association, and other similar statements assuring its continued compliance with their legal obligations, Defendants

---

[106] Eric Heisig, *Pharmacies Across Ohio Received Large Amounts of Painkillers as Opioid Epidemic Ramped Up*, (Aug. 1, 2019), https://www.cleveland.com/metro/2019/07/pharmacies-across-ohio-received-large-amounts-of-painkillers-as-opioid-epidemic-ramped-up.html

[107] *Id.*

[108] Rite Aid, Pharmacy, Health Information, https://www.riteaid.com/pharmacy/health-information

[109] Brief for HDMA and NACDS, 2016 WL 1321983, at *3-4, 25.

not only acknowledged that they understood their obligations under the law, but further affirmed that their conduct was in compliance with those obligations. In doing so, Defendants further delayed efforts to address the growing opioid epidemic.

494. Through the above statements and others, Defendants not only acknowledged that they understood their obligations under the law, but created the false and misleading impression that their conduct was in compliance with those obligations.

G. Multiple Enforcement Actions against the Chain Pharmacies Confirms their Compliance Failures.

495. The Chain Pharmacies have long been on notice of their failure to abide by state and federal law and regulations governing the distribution and dispensing of prescription opioids. Indeed, several of the Chain Pharmacies have been repeatedly penalized for their illegal prescription opioid practices. Upon information and belief, based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the Chain Pharmacies.

i. CVS

496. CVS is one of the largest companies in the world, with annual revenue of more than $150 billion. According to news reports, it manages medications for nearly 90 million customers at 9,700 retail locations. CVS could be a force for good in connection with the opioid crisis, but like other Defendants, CVS sought profits over people.

497. CVS is a repeat offender and recidivist: the company has paid fines totaling over $40 million as the result of a series of investigations by the DEA and the United States Department of Justice ("DOJ"). It nonetheless treated these fines as the cost of doing business and has allowed its pharmacies to continue dispensing opioids in quantities significantly higher than any plausible

medical need would require, and to continue violating its recordkeeping and dispensing obligations under the CSA.

498. Confirming its systemic failures to implement and adhere to adequate controls against diversion, CVS has repeatedly faced enforcement actions. Just this week, CVS's Omnicare subsidiary agreed to pay a $15.3 million civil penalty as part of a settlement with the DEA resolving allegations that it improperly dispensed opioids and other controlled substances to long-term care facilities without a valid prescription.

499. As recently as March 2019, CVS Pharmacy, Inc. (including all of its relevant subsidiaries and affiliates) entered into a $535,000 settlement with the U.S. Attorney's Office for the District of Rhode Island, acting on behalf of the United States and the DEA's Providence Office. In connection with the settlement, a DEA agent stated: "Pharmacies put patients at risk when they dispense Schedule II narcotics, which have the highest potential for abuse, without a valid and legal prescription.[110]

500. In August of 2018, CVS paid $1 million to resolve allegations that CVS pharmacies throughout the Northern District of Alabama violated record-keeping requirements under the CSA and its implementing regulations, the largest civil fine paid in Alabama by a DEA registrant.

501. In June of 2018, CVS paid $1.5 million to resolve allegations that CVS pharmacies in Long Island, New York failed to timely report the loss or theft of controlled substances, including hydrocodone, recognized as one of the most commonly diverted controlled substances.

[110] https://www.dea.gov/press-releases/2019/04/16/cvs-pay-535000-filling-invalid-prescriptions

502. In July 2017, CVS entered into a $5 million settlement with the U.S. Attorney's Office for the Eastern District of California regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances.[111]

503. This fine was preceded by numerous others throughout the country.

504. In February 2016, CVS paid $8 million to settle allegations made by the DEA and the DOJ that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties under the CSA and filling prescriptions with no legitimate medical purpose.

505. In October 2016, CVS paid $600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.

506. In September 2016, CVS entered into a $795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs.

507. In June 2016, CVS agreed to pay the DOJ $3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances—mostly addictive painkillers—more than 500 times between 2011 and 2014.

508. In August 2015, CVS entered into a $450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions

[111] Press Release, U.S. Attorney's Office E. Dist. of Cal., *CVS Pharmacy Inc. Pays $5M to Settle Alleged Violations of the Controlled Substance Act*, U.S. Dep't of Just. (July 11, 2017), https://www.justice.gov/usao-edca/pr/cvs-pharmacy-inc-pays-5m-settle-alleged-violations-controlled-substance-act.

with invalid DEA numbers, and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally permitted to prescribe that drug. Additionally, the government alleged that CVS had recordkeeping deficiencies.

509. In May 2015, CVS agreed to pay a $22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed prescription opioids, "based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need."

510. In September 2014, CVS agreed to pay $1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.

511. In 2013, CVS agree to pay $ 11 million to resolve allegations it violated the CSA and related federal regulations at its retail stores in Oklahoma and elsewhere by: (1) creating and using "dummy" DEA registration numbers on dispensing records, including records provided to state prescription drug monitoring programs; (2) filling prescriptions from prescribers who lacked current or valid DEA numbers; and (3) substituting the DEA number of non-prescribing practitioners for the DEA numbers of prescribers on prescription records.

512. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.

ii. Walgreens

513. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than $118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

514. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history at the time—$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black market sales. These actions demonstrate Walgreens's knowledge of, and disregard for, its obligations to prevent diversion.

515. On September 30, 2009, the DEA issued an Order to Show Cause against a Walgreens retail facility in San Diego, California based in part on allegations that it was dispensing controlled substances, including opioids, to individuals that it knew or should have known were diverting the controlled substances. Although the Order addressed this specific location, the response, including Walgreens's internal assessment of its compliance, or lack thereof, revealed systemic failures from which its Lake County pharmacies would not have been exempt.

516. In April 2011, Walgreens entered into an Administrative Memorandum of Agreement ("2011 MOA") with the DEA arising from the San Diego OTSC and expressly agreed that it would "maintain a compliance program to detect and prevent diversion of controlled substances as required under the Controlled Substances Act ("CSA") and applicable DEA regulations" including regarding the dispensing practices at all of its nationwide pharmacies.

517. On September 14, 2012, however, the DEA also issued an *Order to Show Cause and Immediate Suspension Order* ("ISO"), described above against Walgreens's Distribution Center in Jupiter, Florida, as well as Orders to Show Cause related to certain Walgreens pharmacies. Evidencing the existence of systemic failures, the ISO stated that, "[DEA's] concerns with [Walgreens'] distribution practices are not limited to the six Walgreens pharmacies [discussed in the ISO]."

518. In 2013, Walgreens agreed to the largest settlement in DEA history at the time—$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black-market sales. In addition to the monetary payment, the Jupiter, Florida distribution center lost its authority to distribute or dispense controlled substances, including opioids, for two years. The Department of Justice, in describing the settlement, explained that the conduct at issue included Walgreens's "alleged failure to sufficiently report suspicious orders was a systematic practice that resulted in at least tens of thousands of violations and allowed Walgreens's retail pharmacies to order and receive at least three times the Florida average for drugs such as oxycodone."[112]

519. The settlement resolved investigations into, and allegations of, CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

[112] Press Release, U.S. Attorney's Office S. Dist. of Fla., *Walgreens Agrees To Pay A Record Settlement Of $80 Million For Civil Penalties Under The Controlled Substances Act*, U.S. Dep't of Just. (June 11, 2013), https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled.

520. As part of the 2013 MOA described above, Walgreens "acknowledge[d] that certain Walgreens retail pharmacies did on some occasions dispense certain controlled substances in a manner not fully consistent with its compliance obligations under the CSA . . . and its implementing regulations."[113] The 2013 MOA required Walgreens to, among other things, "maintain a compliance program in an effort to detect and prevent diversion of controlled substances" as required by law.[114]

521. Walgreens's Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens's Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.

522. They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens corporate officers not only turned a blind eye, but provided pharmacists with incentives through a bonus program that compensated them based on the number of prescriptions filled at the pharmacy.- Yet Walgreens corporate officers turned a blind eye to these abuses. In fact, the long term Controlled Substance Compliance Officer at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens's attitude that profit outweighed compliance with the CSA or the health of communities. [115]

---

[113] WAGMDL00490963 at WAGMDL00490964.
[114] *Id.* at WAGMDL00490968.
[115] WAGFLDEA00001890; WAGMDL00815828;WAGFLDEA00000127.

523. Walgreens's settlement with the DEA stemmed from the DEA's investigation into Walgreens's distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Defendant Walgreens's corporate headquarters pushed to increase the number of oxycodone sales to Walgreens's Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center, a distribution center that also distributed into the County.

524. An August 2013 email shows Walgreens understood the consequences of its actions, explaining that Walgreens's "previous system would continue to send additional product to the store without limit or review which made possible the runaway growth of dispensing products like Oxycodone."[116]

525. Walgreens has also settled with a number of state attorneys general, including West Virginia ($575,000) and Massachusetts ($200,000).

526. The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk.

527. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and didn't use sound professional judgment when dispensing opioids and other controlled substances—despite the

[116] WAGMDL00021425

context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay $200,000 and follow certain procedures for dispensing opioids.

528. The actions against Walgreens as both a distributor and a retail pharmacy demonstrate it routinely, and as a matter of standard operating procedure, violated its legal obligations under the CSA and other laws and regulations governing the distribution and dispensing of prescription opioids.

iii. Rite Aid

529. With approximately 4,600 stores in 31 states and the District of Columbia, Rite Aid is the largest drugstore chain on the East Coast and the third-largest in the United States, with annual revenue of more than $21 billion.

530. Confirming its systemic failures to implement and adhere to adequate controls against diversion, Rite Aid has repeatedly faced enforcement actions. In addition to those listed in the Third Amended Complaint, as recently as January 2019, it paid $177,000 into the Naloxone Fund for the State of Massachusetts to resolve allegations that failed to follow regulations designed to prevent substance use disorder in its dispensing of controlled substances, including opioids. Evidencing the systemic nature of the problem, Rite Aid, as part of the agreement, agreed to improve its dispensing practices.

531. In 2018, Rite Aid also agreed to pay a $300,000 settlement for filling Schedule III controlled substances prescriptions in excess of the maximum dosage units allowed to be dispensed at one time.

532. In 2017, Rite Aid paid $834,200 in civil penalties to resolve allegations by the DEA that Rite Aid pharmacies in Los Angeles dispensed controlled substances in violation of the CSA. The DEA's "investigation revealed the incorrect or invalid registration numbers were used at least

1,298 times as a result of Rite Aid's failure to adequately maintain its internal database."[117] Further evidencing the lack of internal controls, the settlement also "resolve[d] allegations that Rite Aid pharmacies dispensed, on at least 63 occasions, prescriptions for controlled substances written by a practitioner whose DEA registration number had been revoked by the DEA for cause."[118]

533. In 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid and nine of its subsidiaries in eight states were fined $5 million in civil penalties for its violations of the CSA.

534. The investigation revealed that from 2004 onwards, Rite Aid pharmacies across the country had a pattern of non-compliance with the requirements of the CSA and federal regulations that lead to the diversion of prescription opioids in and around the communities of the Rite Aid pharmacies investigated. Rite Aid also failed to notify the DEA of losses of controlled substances in violation of 21 USC 842(a)(5) and 21 C.F.R 1301.76(b).

iv. Walmart

535. In addition to the actions described above against Walmart, a prosecution against a Virginia prescriber revealed failures at Walmart pharmacies from 2007 to 2012. A Decision and Order in that case revealed that a Walmart pharmacy would fill prescriptions pursuant to a telephone message from a staff member of the prescriber, purportedly on behalf of the prescriber, even though she failed to provide the prescriber's DEA number. Despite the absence of information required by DEA regulations, the Walmart pharmacy would fill the prescription.[119]

---

[117] DEA, *Rite Aid Pays $834,200 Settlement for Alleged Controlled Substances Act Violations in Los Angeles* (March 9, 2017), https://www.dea.gov/press-releases/2017/03/09/rite-aid-pays-834200-settlement-alleged-controlled-substances-act

[118] *Id.*

[119] DOJ, DEA, Docket No. 15-26, [FR Doc. No. 2017-13158] Peter F. Kelly, D.P.M.; Decision and Order, https://www.deadiversion.usdoj.gov/fed_regs/actions/2017/fr0623.htm

By mid-November of 2008, three Walmart pharmacies had dispensed more than 200 hydrocodone prescriptions and refills on behalf of the prescriber. In 2012, the prescriber learned that someone was fraudulently using his DEA number. He called a Walmart pharmacy regarding refill requests faxed from his office, and advised "that somebody was fraudulently using [his] DEA number."[120] Although he asked that his DEA number be blocked, the same pharmacy still filled two prescriptions on his behalf after this alert. Although Walmart did not face sanctions for its conduct, the Opinion and Order described "the fact that prescriptions which were missing [the] Respondent's DEA number were routinely filling notwithstanding that they were facially invalid," and "that the prescriptions were for hydrocodone in quantities and dosings that were clearly outside the scope of what is usually prescribed by podiatrists" as "deeply disturbing."[121]

536. Federal prosecutors had also taken action against five Walmart and Sam's Club Pharmacies in Texas, alleging that they failed to keep records required to help prevent diversion of controlled substances as required by the CSA. Specifically, "accountability audits did not match the drugs on hand, revealing major overages and shortages in the accountability of controlled substances, and there were missing invoices for controlled substances all in violation of the CSA."[122] A U.S. Attorney further explained that "[b]ecause of the pharmacies' lack of proper record keeping, a variety of Schedule II, III, IV and V controlled substances were lost or stolen and possibly diverted."[123]

---

[120] https://www.deadiversion.usdoj.gov/fed_regs/actions/2017/fr0623.htm
[121] *Id.*
[122] Associated Press, *Wal-Mart Settles Drug Records Accusation*, (Jan 7, 2009), http://prev.dailyherald.com/story/?id=262762
[123] *Id.*

537. As recently as September 2018, minutes of an Oklahoma State Board of Pharmacy meeting reflect that an Oklahoma "Wal-Mart Pharmacy was charged with multiple violations of state and federal regulations and rules including establishing and maintaining effective controls against diversion of prescription drugs."[124] Walmart agreed to pay a fine to resolve the seven alleged violations.

538. Numerous state and federal drug diversion prosecutions have occurred in which prescription opioid pills were procured from the Chain Pharmacies. The allegations in this Complaint do not attempt to identify all these prosecutions, and the information above is merely by way of example.

539. The litany of state and federal actions against the Chain Pharmacies demonstrate that they routinely, and as a matter of standard operation procedure, violated their legal obligations under the CSA and other laws and regulations that govern the distribution and dispensing of prescription opioids.

540. Throughout the country and in Lake County in particular, the Chain Pharmacies were or should have been aware of numerous red flags of potential suspicious activity and diversion.

541. On information and belief, from the catbird seat of their retail pharmacy operations, the Chain Pharmacies knew or reasonably should have known about the disproportionate flow of opioids into the County and the operation of "pill mills" that generated opioid prescriptions that, by their quantity or nature, were red flags for if not direct evidence of illicit supply and diversion. Additional information was provided by news reports, and state and federal regulatory actions, including prosecutions of pill mills in the area.

[124] https://www.ok.gov/pharmacy/documents/Min%20September%202018.pdf

542. On information and belief, the Chain Pharmacies knew or reasonably should have known about the devastating consequences of the oversupply and diversion of prescription opioids, including spiking opioid overdose rates in the community.

543. On information and belief, because of (among other sources of information) regulatory and other actions taken against the Chain Pharmacies directly, actions taken against others pertaining to prescription opioids obtained from their retail stores, complaints and information from employees and other agents, and the massive volume of opioid prescription drug sale data that they developed and monitored, the Chain Pharmacies were well aware that their distribution and dispensing activities fell far short of legal requirements.

544. The Chain Pharmacies' actions and omission in failing to effectively prevent diversion and failing to identify, and halt suspicious orders have contributed significantly to the opioid crisis by enabling, and failing to prevent, the diversion of opioids.

H. The Opioids the Defendants Sold Migrated into Other Jurisdictions.

545. As the demand for prescription opioids grew, fueled by their potency and purity, interstate commerce flourished: opioids moved from areas of high supply to areas of high demand, traveling across state lines in a variety of ways.

546. First, prescriptions written in one state may, under some circumstances, be filled in a different state.- But even more significantly, individuals transported opioids from one jurisdiction specifically to sell them in another.

547. When authorities in states such as Ohio and Kentucky cracked down on opioid suppliers, out-of-state suppliers filled the gaps. Florida in particular assumed a prominent role, as its lack of regulatory oversight created a fertile ground for pill mills. Residents of Ohio and other states would simply drive to Florida, stock up on pills from a pill mill, and transport them back to

home to sell. The practice became so common that authorities dubbed these individuals "prescription tourists."

548. The facts surrounding numerous criminal prosecutions illustrate the common practice. For example, one man from Warren county, Ohio, sentenced to four years for transporting prescription opioids from Florida to Ohio, explained that he could get a prescription for 180 pills from a quick appointment in West Palm Beach, and that back home, people were willing to pay as much as $100 a pill—ten times the pharmacy price. In Columbus, Ohio, a DEA investigation led to the 2011 prosecution of sixteen individuals involved in the "oxycodone pipeline between Ohio and Florida."[125] When officers searched the Ohio home of the alleged leader of the group, they found thousands of prescriptions pills, including oxycodone and hydrocodone, and $80,000 in cash. In 2015, another Columbus man was sentenced for the same conduct—paying couriers to travel to Florida and bring back thousands of prescription opioids, and, in the words of U.S. District Judge Michael Watson, contributing to a "pipeline of death."[126]

549. Outside of Atlanta, Georgia, four individuals pled guilty in 2015 to operating a pill mill; the U.S. attorney's office found that most of the pain clinic's customers came from other states, including North Carolina, Kentucky, Tennessee, Ohio, South Carolina, and Florida. Another investigation in Atlanta led to the 2017 conviction of two pharmacists who dispensed opioids to customers of a pill mill across from the pharmacy; many of those customers were from other states, including Ohio and Alabama.

---

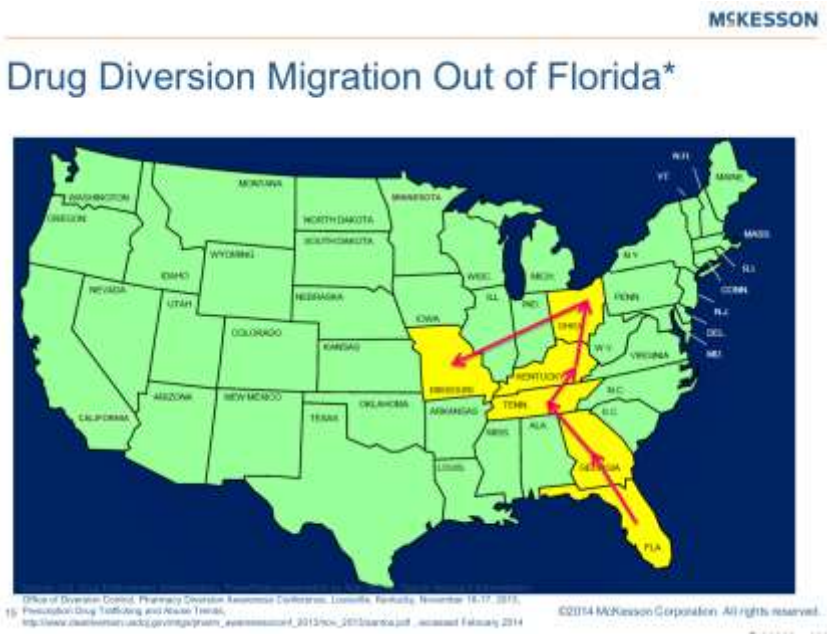
[125] *16 Charged in 'Pill Mill' Pipeline*, Columbus Dispatch (June 7, 2011), http://www.dispatch.com/content/stories/local/2011/06/07/16-charged-in-pill-mill-pipeline.html.

[126] *Leader of Ohio pill-mill trafficking scheme sentenced*, Star Beacon (July 16, 2015), http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html.

550. In yet another case, defendants who operated a pill mill in south Florida were tried in eastern Kentucky based on evidence that large numbers of customers transported oxycodone back to the area for both use and distribution by local drug trafficking organizations. As explained by the Sixth Circuit in its decision upholding the venue decision, "[d]uring its existence, the clinic generated over $10 million in profits. To earn this sum required more business than the local market alone could provide. Indeed, only about half of the [Pain Center of Broward]'s customers came from Florida. Instead, the clinic grew prosperous on a flow of out-of-state traffic, with prospective patients traveling to the clinic from locations far outside Ft. Lauderdale, including from Ohio, Georgia, and Massachusetts."[127] The court further noted that the pill mill "gained massive financial benefits by taking advantage of the demand for oxycodone by Kentucky residents."[128]

551. The route from Florida and Georgia to Kentucky, Ohio, and West Virginia was so well traveled that it became known as the Blue Highway, a reference to the color of the 30mg Roxicodone pills manufactured by Mallinckrodt. Eventually, as police began to stop vehicles with certain out-of-state tags cruising north on I-75, the prescription tourists adapted. They rented cars just over the Georgia state line to avoid the telltale out-of-state tag. If they were visiting multiple pill mills on one trip, they would stop at FedEx between clinics to mail the pills home and avoid the risk of being caught with multiple prescriptions if pulled over. Or they avoided the roads altogether: Allegiant Air, which offered several flights between Appalachia and Florida, was so popular with drug couriers that it was nicknamed the "Oxy Express."[129,]

[127] *United States v. Elliott*, 876 F.3d 855, 858 (6th Cir. 2017).
[128] *Id.* at 861.
[129] *Id.*; *see also* Andrew Welsh-Huggins, *States Take on 'Tourists' Trafficking Painkillers,* Republican Herald (July 9, 2012). Note that Interstate 75 is also called as the Oxy Express; for



552. While the I-75 corridor was well utilized, prescription tourists also came from other states. The director of the Georgia drugs and narcotics agency observed that visitors to Georgia pill mills come from as far away as Arizona and Nebraska.

553. Similar pipelines developed in other regions of the country. For example, the I-95 corridor was another transport route for prescription pills. As the director of the Maine Drug Enforcement Agency explained, the oxycodone in Maine was coming up extensively from Florida, Georgia and California. And according to the FBI, Michigan plays an important role in the opioid epidemic in other states; opioids prescribed in Michigan are often trafficked down to West Virginia, Ohio, and Kentucky.

554. Along the West Coast, over a million pills were transported from the Lake Medical pain clinic in Los Angeles and cooperating pharmacies to the City of Everett, Washington. Couriers drove up I-5 through California and Oregon, or flew from Los Angeles to Seattle. The

example, the Peabody Award-winning documentary by that name focuses on the transport of prescription opioids along I-75. https://www.youtube.com/watch?v=wGZEvXNqzkM.

Everett-based dealer who received the pills from southern California wore a diamond necklace in the shape of the West Coast states with a trail of green gemstones—the color of 80-milligram OxyContin—connecting Los Angeles and Washington state.

555. Abundant evidence, thus, establishes that prescription opioids migrated between cities, counties, and states, including into Ohio from West Virginia, Kentucky, Illinois, Georgia, and Florida. As a result, prescription data from any particular jurisdiction does not capture the full scope of the misuse, oversupply and diversion problem in that specific area. As the criminal prosecutions referenced above show, if prescription opioid pills were hard to get in one area, they migrated from another. The manufacturers and distributors were fully aware of this phenomenon and profited from it.

I. Ohio-Specific Facts

1. Defendants Breached Their Duties in Ohio.

556. In addition to the duties imposed by federal law, under Ohio law, distributors have a duty to detect, investigate, refuse to fill, and report suspicious orders of opioids. To that end, the Ohio Pharmacy Board requires that drug wholesalers "shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of dangerous drugs," and that, as a minimum requirement of wholesale distribution in this State, "[a] system

shall be designed and operated to disclose orders for controlled substances and other dangerous drugs subject to abuse." Ohio Administrative Code § 4729-9-16(H) (emphasis added); R.C. 4729.52 (requiring licensed wholesale distributors to comply with Ohio Board of Pharmacy security regulations); *accord* 21 U.S.C. § 823 (mandating that registration be consistent with the public interest, which, in turn, requires "maintenance of effective controls against diversion . . . into other than lawful medical, scientific, or industrial channels" and "compliance with applicable State and local law"); 21 C.F.R. § 1301.74 (imposing duty to monitor, detect, investigate, refuse to fill, and report suspicious orders under federal law).

557. Ohio regulations further mandate that suspicious orders, defined as unusual in size or frequency or deviation from buying patterns, be reported to the Ohio Board of Pharmacy: "The wholesaler shall inform the state board of pharmacy of suspicious orders for drugs when discovered. Suspicious orders are those which, in relation to the wholesaler's records as a whole, are of unusual size, unusual frequency, or deviate substantially from established buying patterns." Ohio Administrative Code § 4729-9-16(H)(1)(e) et seq. (emphasis added); see also id. §§ 4729-9-12(G) & 4729-9-28(E). Any of the red flags identified by law trigger a duty to report, but this list is not exhaustive. Other factors—such as whether the order is skewed toward high dose pills, or orders that are skewed towards drugs valued for abuse, rather than other high-volume drugs, such as cholesterol medicines— also should alert distributors to potential problems. Distributors also have a duty to know their customers and the communities they serve. To the extent that, through this process of customer due diligence, a distributor observes suspicious circumstances—such as cash transactions or young and seemingly healthy patients filling prescriptions for opioids at a pharmacy they supply—those observations can also trigger reasonable suspicion. A single order

can warrant scrutiny, or it may be a pattern of orders, or an order that is unusual given the customer's history or its comparison to other customers in the area.

558. Defendants were required by Ohio law to operate in compliance with federal laws, including the federal Controlled Substances Act ("CSA"), 21 U.S.C. § 801 *et seq.* and its implementing regulations. *See* Ohio Administrative Code §§ 4729-9-16(L) and 4729-9-28(I) (mandating that "[w]holesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations"). Ohio Pharmacy Board regulations further mandate that "[a] system shall be designed and operated to disclose orders for controlled substances and other dangerous drugs subject to abuse," and that suspicious orders, defined as unusual in size or frequency or deviation from buying patterns, be reported to the Ohio Board of Pharmacy. Ohio Administrative Code §§ 4729-9-16(H); 4729-9-12(G); 4729-9-28(E).

559. As pharmacies, Defendants also have independent duties under Ohio law. The obligations imposed under the Ohio Administrative Code imposes obligations and duties upon "licensees" and "registrants," to "provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs." O.A.C. § 4729-9-05(A) extend to wholesalers, and pharmacies alike.

560. Under the Ohio Administrative Code "[a]n order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law." O.A.C. § 4729-5-21(A); O.A.C. § 4729-5-30(A) (same).

561. Although they act through their agents, the Chain Pharmacies, as the registrants, are ultimately responsible to prevent diversion, as described above. To that end, the Tenth Appellate District of the Court of Appeals of Ohio has determined that the Ohio Administrative

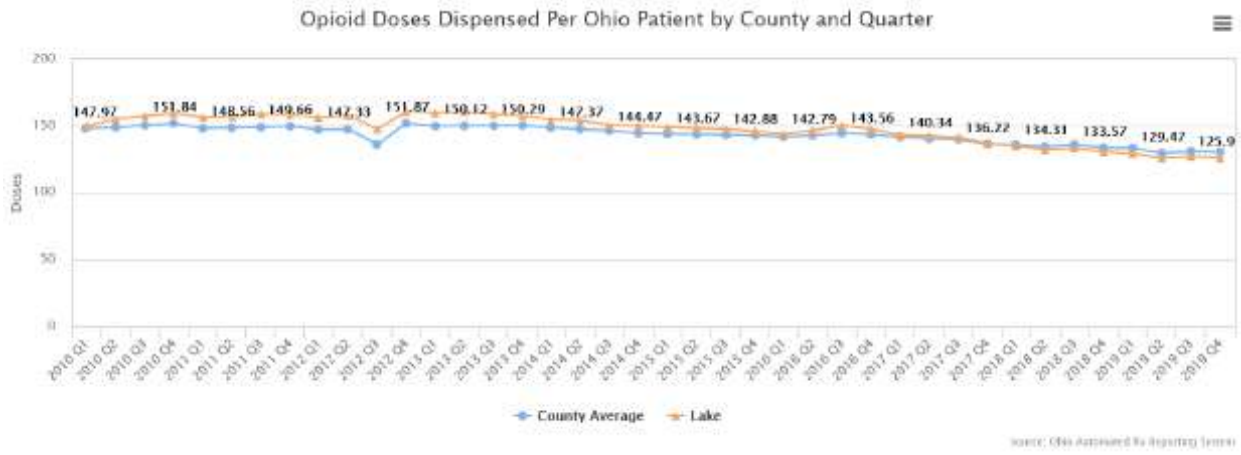
Code "places the ultimate responsibility upon the 'registrant' … to provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs."[130] Further, as described above, the obligations under the controlled-substances laws extend to any entity selling prescription opioids, whether it is the registration-holder or not.

562. Thus, in addition to their duties as distributors, the Chain Pharmacies also had a duty to design and implement systems to prevent diversion of controlled substances in their retail pharmacy operations. The Chain Pharmacies had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

2. The Opioid Epidemic in Ohio and the County

563. A number of Ohio counties had an opioid prescription rate exceeding their population, and at times well in excess of their population, for extended periods of time.

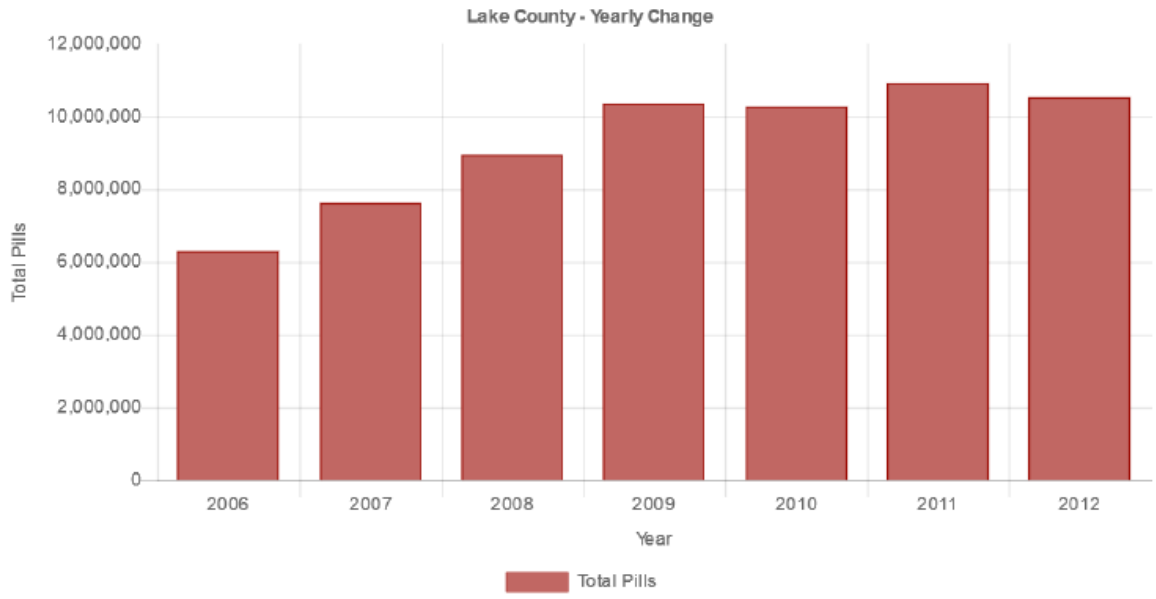
564. Even in one of the states hardest hit by the opioid epidemic, opioid doses dispensed per patient exceeded statewide averages from 2010 through 2018.



[130] *Linden Med. Pharm. v. Ohio State Bd. of Pharm.*, 2001 Ohio App. LEXIS 2041, at *24 (Ohio Ct. App. 11th Dist. May 8, 2001) (explaining that licensees electing to operate a business through employees are responsible to the licensing authority for their conduct").

565. ARCOS data disclosed in this MDL reveals millions of pills flowing through the County in 2006-2012 as well.

Lake County: Year-over-year Change

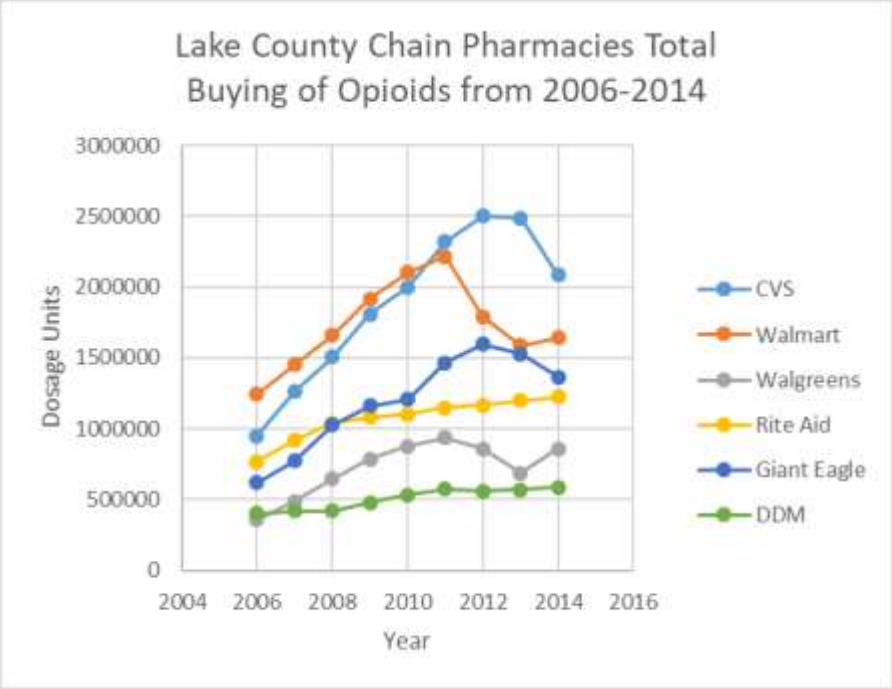


	2006	2007	2008	2009	2010	2011	2012
Total Pills	6,292,890	7,618,710	8,942,820	10,353,240	10,270,290	10,917,750	10,532,400

566. Given this, and the additional red flags described below, Defendants should have been on notice that the diversion of opioids was likely occurring in and around Lake County, should have investigated, ceased filling orders for opioids, and reported potential diversion to law enforcement.

567. Publicly available data suggests distribution of opioids to Lake County exceeded reasonable medical use and that opioids were likely diverted into the County. As described above, the volume of opioids distributed and dispensed by each Defendant in the County is so high as to raise a red flag that not all of the prescriptions being ordered could be for legitimate medical uses.

568. As described above, Defendants were responsible for a large share of this volume. Even amidst an epidemic, they maintained and even grew the volume of opioids they purchased, and by extension dispensed. As further described above, much of this volume was self-distributed.



569. Walgreens, for example, also knew of prescribers with problematic prescribing patterns. Instead of recognizing, or stopping, the harm they were causing through sales from these prescribers, Walgreens tried to preserve them. One employee for example, sought "help" from a pharmacy manger to "not lose any more sales" of the highest strength, 80mg OxyContin pills, prescribed by Dr. Yokiel in Lake County:

From: Pharmacy Manager 05821 [mailto:rxm.05821@store.walgreens.com]
Sent: Friday, March 08, 2013 9:57 AM
To: Whited, Jaime
Subject: oxycontin 80mg

Jaime,

was wondering how to fix this so that i don't lose any more sales. I have a patient on oxycontin 80mg #84 every month from dr yokiel. i have 82 on hand and have had to turn him away the past 2 months to rite aid. since i am not generating any movement the drug is not being auto ordered, this is one of the drugs that i believe they won't let me pdq and if i add it to my c2 order it will be deleted.

please help!!!
Erin

A Walgreens chart list the same doctor as a top prescriber, as does a metric report for a Cuyahoga CVS.

570. In addition, the increase in fatal overdoses from prescription opioids has been widely publicized for years. The CDC estimates that for every opioid-related death, there are 733 non-medical users. Defendants thus had every reason to believe that illegal diversion was occurring in Lake County.

571. Not only were prescription opioids diverted within the County, upon information and belief, they were being diverted into the County from Southern Ohio pill mills that, upon information and belief, Defendants also failed to report or cease supplying. An epidemiological report from the Ohio Governor's Cabinet opiate action team cited the shutdown of southern Ohio pill mills as one of the chief factors in an increase throughout Ohio in heroin overdose rates (which, as explained below, is the drug turned to by prescription opioid users when those drugs are no longer available or too expensive). In Lake County, 240 people have lost their lives to heroin or fentanyl overdoses from 2013 to 2017 alone.

572. Based upon all of these red flags, it can be fairly inferred that each of the Defendants disregarded their reporting and due diligence obligations under Ohio law in and affecting the Plaintiff. Instead, they consistently failed to report or suspend illicit orders, deepening the crisis of opioid abuse, addiction, and death in Ohio and Lake County.

3. Defendants Have Created a Public Health Crisis in the County.

573. Ohio is among the states hardest hit by the opioid epidemic. "Opioid addiction, abuse, and overdose deaths have become the most pressing public health issue facing Ohio."[131] Ohio in 2017 "led the country in drug overdose deaths per capita, a rate that continues to rise,

[131] C. William Swank Program in Rural-Urban Policy, Taking Measure of Ohio's Opioid Crisis, The Ohio State University (Oct. 2017) at 1.

overwhelming families, communities, and local governments across the state." Overdose deaths have become the leading cause of death for Ohioans under the age of 55, and across all ages, more than two and a half times as many people die from drug overdoses as from car accidents. Most of the overdose fatalities in Ohio involved opioids.

574. In Ohio, an average of 14 people have died, per day, from fatal drug overdoses. Provisional data from the CDC showed the crisis continuing to explode during the first half of 2017, with 5,232 Ohio overdose deaths recorded in the 12 months ending June 31, 2017. Most of the overdose fatalities in Ohio involved opioids. According to a recent study, in the seven years from 2010 to 2016, in Ohio, more than half a million "years of lost life" are attributable to opioid overdoses.[132] The same study concluded that, in 2016, "opioid overdose lowered the lifespan of an average Ohioan by 0.97 years."[133] In 2018, Opioids were involved in 46,802 overdose deaths in Ohio—nearly 70% of all overdose deaths. These grim numbers likely understate the number of lives lost due to incomplete reporting.

575. Tragically, "Ohio's death rate has grown faster than the national rate."[134] From 2000 to 2012, the State experienced a more that 366% increase in drug overdose deaths, a startling statistic driven largely by overdoses from prescription drugs. Measured from 2000 to 2015, the numbers are even more staggering: the rate of unintentional drug poisonings in Ohio jumped

---

132 https://journals.lww.com/journaladdictionmedicine/fulltext/2020/04000/years_of_life_lost_due_to_opioid_overdose_in_ohio_.12.aspx

133 Hall, O. Trent DO; Hall, Orman E. MA; McGrath, Ryan P. PhD; Haile, Zelalem T. PhD, Years of Life Lost due to Opioid Overdose in Ohio, Temporal and Geographic Patterns of Excess Mortality, Journal of Addiction Medicine: March/April 2020 - Volume 14 - Issue 2 - p 156-162, doi: 10.1097/ADM.0000000000000554, https://journals.lww.com/journaladdictionmedicine/fulltext/2020/04000/years_of_life_lost_due_to_opioid_overdose_in_ohio_.12.aspx

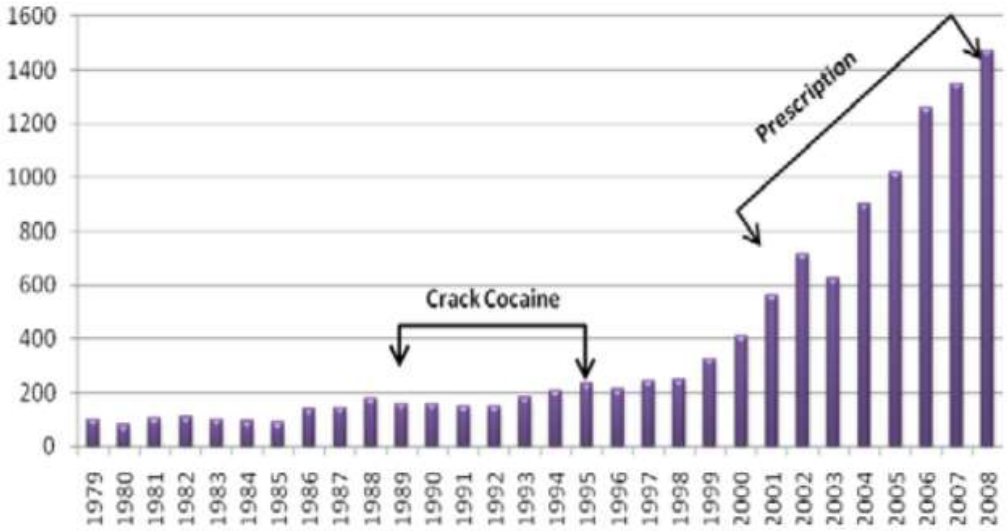
134 *Id.*

642%, with the increase driven largely by opioid-related overdoses. In 2015, there were 3,050 Ohio overdose deaths, up 20.5% from 2,531 Ohio overdose deaths in 2014. Eighty-five percent of these overdoses involved opioids.

576. Between 2015 and 2016, overdose deaths in Ohio rose by nearly 33% to 4,329 people. Reports from death certifications show that the overall number of drug overdose deaths attributable to all opioids rose from 85% in 2015 to 86.3% in 2016.

577. These figures make the opioid epidemic in Ohio one of the most deadly epidemics the state has faced, measured by deaths and mortality rates. In 2010, mortality rates were four to

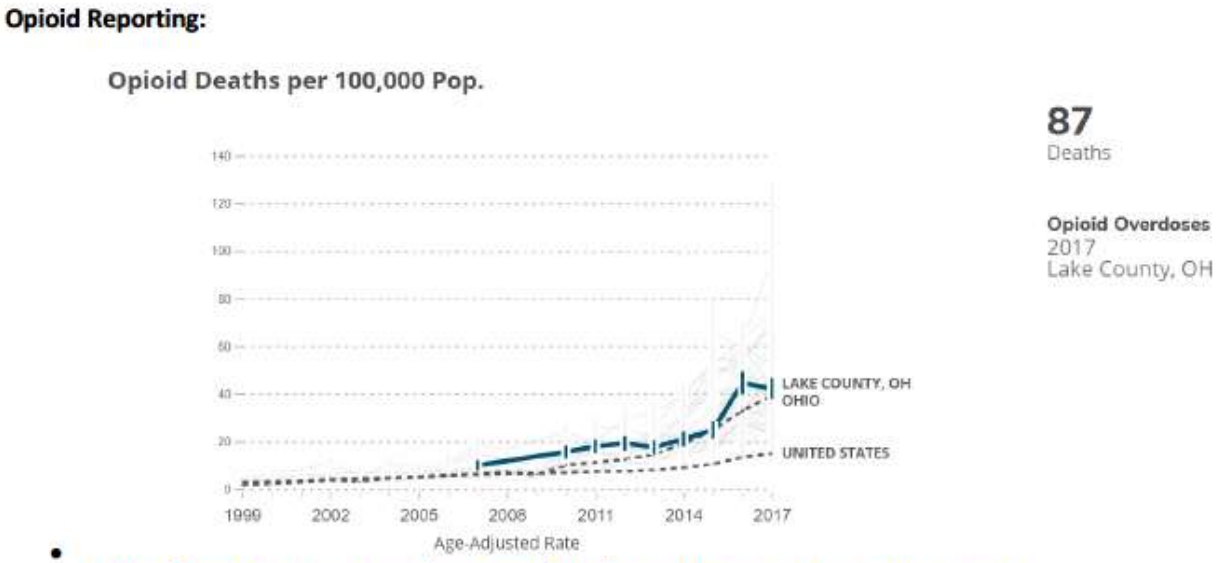
Figure 4. Epidemics of unintentional drug overdoses in Ohio, 1979-2008.[12,13,14]



five times higher than the rates during the "black tar" heroin epidemic in the mid-1970s and more than three times what they were during the peak years of the crack cocaine epidemic in the early 1990s. To quote one Ohio medical examiner: we are currently suffering a "slow-moving mass fatality that occurred last year, is occurring again this year, and will occur again next year."[135]

[135] Testimony of Dr. Thomas P. Gilson, Chief Medical Examiner of Cuyahoga County, Hearing of the U.S. Permanent Subcommittee on Investigations, of the Senate Committee on Homeland

578. Even in the midst of such staggering statewide statistics, Lake County stands out. Even as the County and its residents have worked to save lives, in 2017 alone, 87 people in Lake County still lost their lives to opioid overdoses.



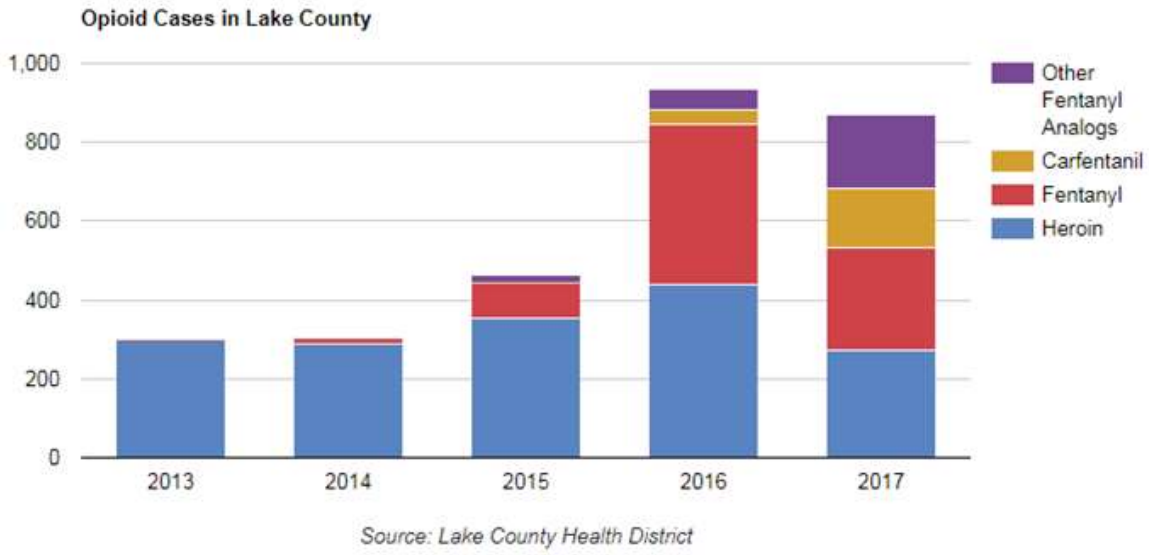
579. In addition to the death that has plagued Lake County, County resources have been depleted due to Lake County's efforts in combating this epidemic.

580. In response to the epidemic, Lake County has created the Lake County Opiate Task Force, which is a collaboration between courts, law enforcement, first responders, education, Coroner, Health District and the Department of Job and Family Services. The Task Force is committed to reduce the tragic consequences that result from the use of opiates in Lake County.

Security and Government Affairs, Subject, Public Health Emergency Stemming from Opiate/Opioid Crisis, https://www.google.com/search?source=hp&ei=dXLeWsSRJYSc_Qbgi5DQBw&q=slow-moving+mass+fatality+that+occurred+&oq=slow-moving+mass+fatality+that+occurred+&gs_l=psy-ab.3...632.632.0.1184.1.1.0.0.0.0.89.89.1.1.0....0...1c.1.64.psy-ab..0.0.0....0.Lr59Z68SFFY

581. Lake County has also created a "Quick Response Team" which works to connect more people who are struggling in Lake County with addiction with treatment services.

582. Between 2013 and 2018, opioid cases handled by the Lake County crime lab nearly tripled, from 296 cases in 2013 to 868 cases in 2017:[136]



583. A study by the Ohio Substance Abuse Monitoring Network reported on the connection between oxycodone use and heroin addiction, fording that "young new heroin abusers seeking treatment reported OxyContin abuse prior to becoming addicted to heroin," often after OxyContin became too expensive or difficult to obtain."

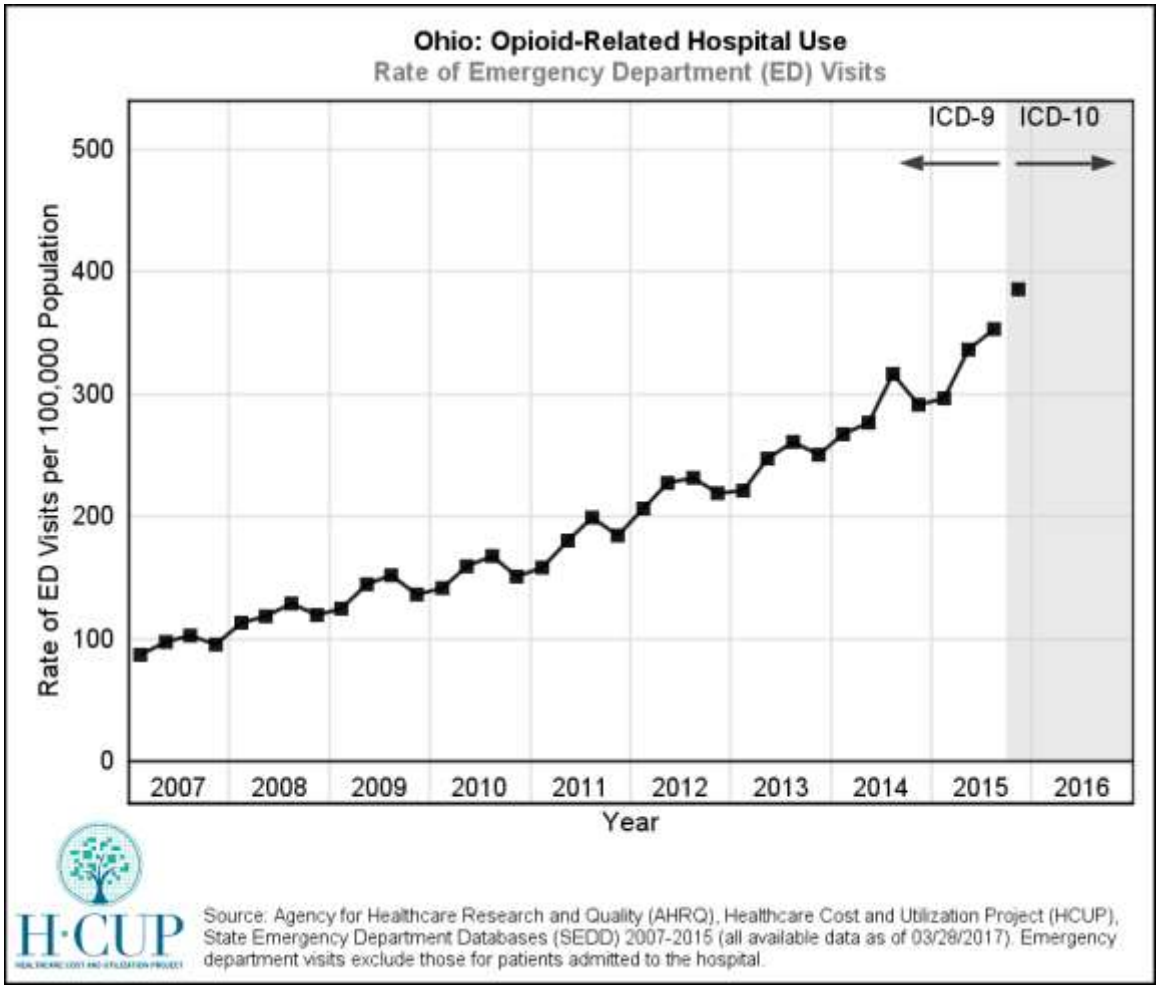
584. Carfentanil, a powerful derivative of fentanyl, has increasingly been found in heroin and fentanyl sold illicitly. Carfentanil is so strong that it is typically used in veterinary medicine to sedate large wild animals such as elephants, and has been researched as a chemical weapon.

[136] https://www.americancommunities.org/how-an-ohio-middle-suburb-is-tackling-its-opioid-epidemic/

Because of its potency, the Ohio Attorney General's website recommends that chemists and lab technicians who test for carfentanil use protective gear.

585. So deadly is this trend that surges of fatal drug overdoses have outpaced the capacity of some local morgues. Coroners or medical examiners from at least four Ohio communities— Cuyahoga, Ashtabula, Summit, and Stark Counties— have had to request the use of a refrigerated trailer known as a "mobile morgue unit" and originally intended for catastrophes leading to mass casualties, from the Ohio Department of Health.

586. Overdose deaths are only one consequence. Opioid addiction and misuse also result in an increase in emergency room visits, emergency responses, and emergency medical technicians' administration of Narcan or naloxone—the antidote to opioid overdose. In fact, while



the rate of opioid-related emergency department visits increased in almost all states from 2009 to 2014, Ohio experienced the greatest increase of any state in the nation, and the rate of opioid-related inpatient stays more than doubled as well, according to data from the Agency of Healthcare Research and Quality.

587. Ohio EMS personnel administered naloxone (or Narcan) more than 44,500 times in 2017 alone. This means that, on average, Ohio EMS personnel administered over 122 doses of naloxone every day in 2017 alone. This information, too, is likely understated, as only 72% of Ohio EMS agencies reported data for inclusion in the state's summary brief.

588. Individuals addicted to opioids are so familiar with the potential for overdose that many choose to use drugs in public places, such as a Walmart bathroom, where they can be found and revived.

589. As communities have worked to save lives, the opioid epidemic has continued to outpace their efforts. Opioid addiction is now the primary reason that Ohioans seek substance abuse treatment. According to addiction programs in the County, a typical course sees addicts requesting more and more opioids from their doctors, who eventually cut them off. Many addicts then doctor-shop for additional prescriptions, and when that source runs out, turn to the streets to buy opioids illicitly. A significant number become heroin addicts. Addiction treatment programs, whose patient populations vary, reported rates of patients who had switched from prescription opioids to heroin ranging from half to 95%. Those addicts who do reach treatment centers often do so when their health, jobs, families and relationships reach the breaking point, or after turning to criminal activity such as prostitution and theft to sustain their addiction. Unfortunately, few are successful in getting and staying clean; repeated relapse is common.

590. Injury and illness in Ohio extends well beyond even overdoses and emergency response. According to the CDC, an increase in Hepatitis C in the United States is directly tied to intravenous injection of opioids. Once again, Ohio is no exception to this trend. The number of cases of chronic Hepatitis C in Ohio nearly tripled from 2011-2015, an increase that resulted largely from intravenous use of drugs, including OxyContin and other prescription painkillers. The co-morbidity is sufficiently high that the Ohio Department of Health recommends that women of childbearing age who have tested positive for drug and dependence also receive screening for Hepatitis C and HIV.

591. The County also has experienced an increase in drug-related crimes and has had to increase its spending on drug-related treatment and prevention, as well as public-safety.

592. Perhaps the most profound effect, though, has been on children orphaned or otherwise displaced by opioids. Children also have been direct victims of opioid overdoses.

593. Statewide, "[c]hildren of parents addicted to opiates," described as the "invisible victims of the epidemic," are "flooding into the state's child protection system."[137] Seventy percent of infants placed in Ohio's foster care system are children of parents with opioid addictions. Children with parents addicted to drugs tend to stay in foster care longer, and they often enter the system having experienced significant trauma related to their parents' addiction, which makes their care more expensive and place the children at greater risk for poor mental and physical health their entire lives. "Child welfare agencies across the state say they're seeing more kids in need of foster care or living with extended family because of opioids."[138]

[137] Public Children Services Association of Ohio (PCSAO), http://www.pcsao.org/programs/opiate-epidemic.

[138] https://radio.wosu.org/post/what-opioid-crisis-costing-mahoning-valley#stream/0

594. These figures do not account for children who are placed in kinship care or who receive public services without being displaced from their homes. Increasingly, relatives have been caring for children impacted by the opioid epidemic. As of May 2017, approximately 124,000 children—5% of the children in the state—were being raised by relatives other than their parents. Even so, public agencies have struggled to find homes for children in need, and "[t]he system's historic reliance on kinship families has been checked because, too often, multiple members of the same family are addicted."[139]

595. According to a report by the Public Children Services Association of Ohio ("PCSAO"), a statewide membership organization for county children services agencies, if children continue to enter foster care at the current rate, by 2020, more than 20,000 Ohio children will be in foster care. Already, Ohio's children's services have reached a state of crisis. Increasing placement costs have sent agencies into significant deficits, at the same time they are also facing recruitment, training and overtime costs due to loss of staff because of burnout, with as many as 1 in 7 caseworkers with zero performance concerns leaving children's services.

596. Ohio has the heaviest reliance on local dollars for child protection services of any state in the nation, with counties shouldering more than half of the costs through local government funds and dedicated levies.

597. In Ohio, the number of infants born with neonatal abstinence syndrome increased six-fold in from 2004 to 2011. From 2009 to 2014, data from seven regional hospitals showed a greater-than six-fold increase in drug-exposed infants. As a whole, the State has seen an 816% increase in the number of infants born with NAS from 2006 to 2015, with opioids and other illegal

[139] Public Children Services Association of Ohio (PCSAO), http://www.pcsao.org/programs/opiate-epidemic.

narcotics being the most commonly implicated drugs since 2009. In 2015 alone, 2,174 infants were admitted to inpatient settings for this painful condition, an average of six per day. NAS has become so prevalent in Ohio communities that the state's Department of Health now recommends screening all newborns for NAS.

598. This dramatic rise in NAS is an epidemic within an epidemic. According to the Ohio Perinatal Quality Collaborative, the "NAS epidemic is steadily increasing, overwhelming social service systems and public payers."[140] In 2013, the average inpatient stay and bill for babies suffering from NAS was four times longer and four times higher than for other infants in Ohio. Newborns with NAS spent approximately 26,000 days in Ohio hospitals in 2014, with health care costs totaling $105 million. These hospitals have lacked the resources to provide a safety net for these families; mothers and babies often are discharged from hospitals without resources to transition them to addiction treatment programs.

599. The costs of this human tragedy cannot be calculated or adequately compensated. But the financial costs that are already known are staggering. These resources are diverted from other important uses and some agencies will likely have to increase operating levies to fund their services, shifting an additional burden to Lake County residents. These costs do not even contemplate the resources necessary to fully address the epidemic.

J. The Defendants Conspired To Engage In The Wrongful Conduct Complained Of Herein and Intended To Benefit Both Independently and Jointly From Their Conspiracy.

600. In addition, and on an even broader level, all Defendants took advantage of the industry structure, including end-running its internal checks and balances, to their collective advantage. Defendants agreed among themselves to increasing the supply of opioids and

[140] Neonatal Abstinence Syndrome Project, OPQC, Ohio Perinatal Quality Collaborative, *available at* https://opqc.net/projects/NAS.

fraudulently increasing the quotas that governed the manufacture and supply of prescription opioids. Defendants did so to increase sales, revenue, and profit from their opioid products.

601. The interaction and length of the relationships between and among the Defendants reflects a deep level of interaction and cooperation between Defendants in a tightly knit industry. Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

602. Defendants collaborated to expand the opioid market in an interconnected and interrelated network in the following ways, as set forth more fully below, including, for example, membership in the NACDS and HDA.

603. Defendants utilized their membership in the NACDS and HDA and other forms of collaboration to form agreements about their approach to their duties under the CSA to report suspicious orders. The Defendants overwhelmingly agreed on the same approach—to fail to identify, report or halt suspicious opioid orders, and fail to prevent diversion. Defendants' agreement to restrict reporting provided an added layer of insulation from DEA scrutiny for the entire industry as Defendants were thus collectively responsible for each other's compliance with their reporting obligations. Defendants were aware, both individually and collectively aware of the suspicious orders that flowed directly from Defendants' facilities.

604. Defendants knew that their own conduct could be reported by other Defendants and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting or suspicious orders to ensure consistency in their dealings with DEA.

605. The Defendants also worked together to ensure that the opioid quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the

DEA in order to ensure that the DEA had not basis for refusing to increase or decrease production quotas due to diversion.

606. The desired consistency, and collective end goal was achieved. Defendants achieved blockbuster profits through higher opioid sales by orchestrating the unimpeded flow of opioids.

K. Statutes Of Limitations Are Tolled and Defendants Are Estopped From Asserting Statutes Of Limitations As Defenses.

1. Continuing Conduct

607. Plaintiff contends it continues to suffer harm from the unlawful actions by the Defendants.

608. The continued tortious and unlawful conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The public nuisance remains unabated. The conduct causing the damages remains unabated.

2. Equitable Estoppel and Fraudulent Concealment

609. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook active efforts to deceive Plaintiff and to purposefully conceal their unlawful conduct and fraudulently assure the public, including the State, the Plaintiff, and Plaintiff's community, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and to continue generating profits. Notwithstanding

the allegations set forth above, the Defendants affirmatively assured the public, including the State, the Plaintiff, and Plaintiff's communities, that they are working to curb the opioid epidemic.

610. The Defendants were deliberate in taking steps to conceal their conspiratorial behavior and active role in the deceptive marketing and the oversupply of opioids through overprescribing and suspicious sales, all of which fueled the opioid epidemic.

611. Defendants also concealed from the County the existence of the County's claims by hiding their lack of cooperation with law enforcement and affirmatively seeking to convince the public that their legal duties to report suspicious sales had been satisfied through public assurances that they were working to curb the opioid epidemic. They publicly portrayed themselves as committed to working diligently with law enforcement and others to prevent diversion of these dangerous drugs and curb the opioid epidemic, and they made broad promises to change their ways insisting they were good corporate citizens. These repeated misrepresentations misled regulators, prescribers and the public, including Plaintiff, and deprived Plaintiff of actual or implied knowledge of facts sufficient to put Plaintiff on notice of potential claims.

612. The County did not discover the nature, scope and magnitude of Defendants' misconduct, and its full impact on the County, and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

613. Further, Defendants have also concealed and prevented discovery of information, including data from the ARCOS database, that will confirm their identities and the extent of their wrongful and illegal activities. On April 11, 2018, the Northern District of Ohio Ordered the transactional ARCOS data be produced, over Defendants' strenuous objections. In so doing, the Court reviewed its previous decisions on this data and held that, because the transaction data had

not yet been produced, the Plaintiffs *could not identify* the potential defendants in this litigation, and further held that such information was "critical":

> This means Plaintiff[s] still do[] not know: (a) which manufacturers (b) sold what types of pills (c) to which distributors; nor do they know (d) which distributors (e) sold what types of pills (f) to which retailers (g) in what locations. In any given case, therefore, the Plaintiff[s] still cannot know for sure who are the correct defendants, or the scope of their potential liability. For example, the ARCOS spreadsheets produced by DEA show the top five distributors of oxycodone in Ohio in 2014 were Cardinal Health, AmerisourceBergen, McKesson, Walmart, and Miami-Luken; but there is no way to know whether (or how much) any of these five entities distributed oxycodone into Seneca County, Ohio (or any other particular venue). . . . [The] DEA and [the] defendants . . . [have] conceded the data was relevant and necessary to litigation . . . . Discovery of precisely which manufacturers sent which drugs to which distributors, and which distributors sent which drugs to which pharmacies and doctors, is critical not only to all of plaintiff[s'] claims, but also to the Court's understanding of the width and depth of this litigation.

Order of April 11, 2018 [Doc. 233] at pp. 6-7 (footnotes omitted).

614. Defendants intended that their actions and omissions would be relied upon, including by Plaintiff and Plaintiff's communities. Plaintiff and Plaintiff's community did not know and did not have the means to know the truth, due to Defendants' actions and omissions.

615. The Plaintiff and Plaintiff's community reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

CAUSES OF ACTION

ELEVENTH CLAIM FOR RELIEF

Common Law Absolute Public Nuisance (Against All Defendants)

616. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein unless inconsistent with the allegations in this Count, and further alleges:

617. Defendants created and maintained a public nuisance which proximately caused injury to Plaintiff.

618. A public nuisance is an unreasonable interference with a right common to the general public.

619. Defendants have created and maintained a public nuisance by marketing, distributing, dispensing, and selling opioids in ways that unreasonably interfere with the public health, welfare, and safety in Plaintiff's community, and Plaintiff and the residents of Plaintiff's community have a common right to be free from such conduct and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person and property.

620. The public nuisance is an *absolute* public nuisance because Defendants' nuisance-creating conduct was intentional and unreasonable and/or violated statutes which established specific legal requirements for the protection of others.

621. Defendants have created and maintained an absolute public nuisance through their ongoing conduct of marketing, distributing, dispensing, and selling opioids, which are dangerously addictive drugs, in a manner which caused prescriptions and sales of opioids to skyrocket in Plaintiff's community, flooded Plaintiff's community with opioids, and facilitated and encouraged the flow and diversion of opioids into an illegal, secondary market, resulting in devastating consequences to Plaintiff and the residents of Plaintiff's community.

622. Defendants know, and have known, that their intentional, unreasonable, and unlawful conduct will cause, and has caused, opioids to be used and possessed illegally and that their conduct has produced an ongoing nuisance that has had, and will continue to have, a detrimental effect upon the public health, welfare, safety, peace, comfort, and convenience of Plaintiff and Plaintiff's communities.

623. Defendants' conduct has created an ongoing, significant, unlawful, and unreasonable interference with rights common to the general public, including the public health, welfare, safety, peace, comfort, and convenience of Plaintiff and Plaintiff's community. *See* Restatement (Second) of Torts § 821B.

624. The interference is unreasonable because Defendants' nuisance-creating conduct:

a. Involves a significant interference with the public health, the public safety, the public peace, the public comfort, and/or the public convenience;

b. At all relevant times was and is proscribed by state and federal laws and regulations; and/or

c. Is of a continuing nature and, as Defendants know, has had and is continuing to have a significant effect upon rights common to the general public, including the public health, the public safety, the public peace, the public comfort, and/or the public convenience.

625. The significant interference with rights common to the general public is described in detail throughout this Complaint and includes:

i. The creation and fostering of an illegal, secondary market for prescription opioids;

ii. Easy access to prescription opioids by children and teenagers;

iii. A staggering increase in opioid abuse, addiction, overdose, injuries, and deaths;

iv. Infants being born dependent on opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts;

v. Employers have lost the value of productive and healthy employees; and

vi. Increased costs and expenses for Plaintiff relating to healthcare services, law enforcement, the criminal justice system, social services, and education systems.

626. Defendants intentionally and unreasonably and/or unlawfully deceptively marketed and pushed as many opioids onto the market as possible, fueling addiction to and diversion of these powerful narcotics, resulting in increased addiction and abuse, an elevated level of crime, death and injuries to the residents of Plaintiff's community, a higher level of fear, discomfort and

inconvenience to the residents of Plaintiff's community, and direct costs to Plaintiff and Plaintiff's community.

627. Each Defendant is liable for creating the public nuisance because the intentional and unreasonable and/or unlawful conduct of each Defendant was a substantial factor in producing the public nuisance and harm to Plaintiff.

628. A violation of any rule or law controlling the sale and/or distribution of a drug of abuse in Plaintiff's community constitutes an absolute public nuisance. *See e.g.* R.C. § 4729.35 ("The violation by a . . . person of any laws of Ohio or of the United States of America or of any rule of the board of pharmacy controlling the distribution of a drug of abuse . . . constitute[s] a public nuisance[.]").

629. In the sale distribution, and dispensation of opioids in Ohio and Plaintiff's community, Defendants violated federal law, including, but not limited to, 21 U.S.C.A. § 823 and 21 C.F.R. § 1301.74, and Ohio law, including, but not limited to, R.C. § 4729.01(F), R.C. §§ 4729.51-4729.53, and O.A.C. §§ 4729-9-12, 4729-9-16, and 4729-9-28, and 4729-9-05(A).

630. Defendants' unlawful nuisance-creating conduct includes violating federal and Ohio statutes and regulations, including the controlled substances laws, by

a. Distributing, dispensing, dispensing, and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b. Distributing, dispensing, and selling without maintaining effective controls against the diversion of opioids;

c. Choosing not to effectively monitor for suspicious orders;

d. Choosing not to investigate suspicious orders;

e. Choosing not to report suspicious orders;

f. Choosing not to stop or suspend shipments of suspicious orders;

g. Distributing, dispensing, and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills;"

h. Defendants' intentional and unreasonable nuisance-creating conduct, for which the gravity of the harm outweighs the utility of the conduct, includes:

i. Distributing, dispensing, and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

j. Distributing and dispensing, opioids without maintaining effective controls against the diversion of opioids;

k. Choosing not to effectively monitor for suspicious orders;

l. Choosing not to investigate suspicious orders;

m. Choosing not to report suspicious orders;

n. Choosing not to stop or suspend shipments of suspicious orders; and

o. Distributing, dispensing, and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

631. Defendants intentionally and unreasonably distributed, dispensed, and sold opioids that Defendants knew would be diverted into the illegal, secondary market and would be obtained by persons with criminal purposes.

632. In the distribution, dispensation, and sale of opioids in Ohio and Plaintiff's community, Defendants violated and/or aided and abetted violations of R.C. § 2925.02(A), which states:

> "No person shall knowingly do any of the following:
>
> (1) By force, threat, or deception, administer to another or induce or cause another to use a controlled substance; . . . or
>
> (3) By any means, administer or furnish to another or induce or cause another to use a controlled substance, and thereby cause serious physical harm to the other person, or cause the other person to become drug dependent."

633. Defendants are in the business of distributing, and/or dispensing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because *inter alia* these drugs are defined under federal and state law as substances posing a high potential for abuse and addiction.

634. Indeed, opioids are akin to medical-grade heroin. Defendants' wrongful conduct of deceptively marketing and pushing as many opioids onto the market as possible led directly to the public nuisance and harm to Plaintiff—exactly as would be expected when medical-grade heroin in the form of prescription opioids are deceptively marketed, flood the community, and are diverted into an illegal, secondary market.

635. Defendants had control over their conduct in Plaintiff's community and that conduct has had an adverse effect on rights common to the general public. Defendants had control over their own shipments of opioids and over their reporting, or lack thereof, of suspicious prescribers and orders. Each of the Defendants controlled the systems they developed to prevent diversion, whether they filled orders they knew or should have known were likely to be diverted or fuel an illegal market.

636. It was reasonably foreseeable that Defendants' actions and omissions would result in the public nuisance and harm to Plaintiff described herein.

637. Because of Defendants' special positions within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

638. The public nuisance created by Defendants' actions is substantial and unreasonable. It has caused and continues to cause significant harm to Plaintiff's community and the harm inflicted outweighs any offsetting benefit.

639. The externalized risks associated with Defendants' nuisance-creating conduct as described herein greatly exceed the internalized benefits.

640. As a direct and proximate result of Defendants' tortious conduct and the public nuisance created by Defendants, Plaintiff has suffered and will continue to suffer economic damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections, rehabilitation, and other services.

641. As a direct and proximate result of Defendants' tortious conduct and the public nuisance created by Defendants, Plaintiff has suffered and will continue to suffer stigma damage, non-physical property damage, and damage to its proprietary interests.

642. The nuisance created by Defendants' conduct is abatable.

643. Defendants' misconduct alleged in this case is ongoing and persistent.

644. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

645. Plaintiff has incurred expenditures for special programs over and above Plaintiff's ordinary public services.

646. Plaintiff seeks to abate the nuisance created by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing, and persistent actions and omissions and unreasonable interference with rights common to the general public.

647. Plaintiff has suffered, and will continue to suffer, unique harms as described in this Complaint, which are of a different kind and degree than Ohio citizens at large. These are harms that can only be suffered by Plaintiff.

648. Plaintiff is asserting their own rights and interests and Plaintiff's claims are not based upon or derivative of the rights of others.

649. The tortious conduct of each Defendant was a substantial factor in creating the absolute public nuisance.

650. The tortious conduct of each Defendant was a substantial factor in producing harm to Plaintiff.

651. Plaintiff has suffered an indivisible injury as a result of the tortious conduct of Defendants.

652. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.

653. Plaintiff asserts this Cause of Action as a common law tort claim for absolute public nuisance and not as a "product liability claim" as defined in R.C. § 2307.71. In this Count, Plaintiff does not seek damages for death, physical injury to person, emotional distress, or physical damages to property, as defined under the Ohio Product Liability Act.

654. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre and post-judgment interest.

PRAYER FOR RELIEF

655. Plaintiff respectfully requests that this Court enter an order of judgment granting all relief requested in this complaint, and/or allowed at law or in equity, including:

p. abatement of the nuisance;

q. equitable and injunctive relief in the form of Court-enforced corrective action;

r. attorneys' fees;

s. costs and expenses of suit;

t. pre- and post-judgment interest; and

u. such other and further relief as this Court deems appropriate.

JURY DEMAND

Plaintiff requests a jury be seated to try all issues of fact and law presented herein.

By: /s/ Hunter Shkolnik

Dated: May 15, 2020

PLEVIN, & GALLUCCI COMPANY, L.P.A.

/s/ Frank Gallucci
Frank Gallucci (0072680)
55 Public Square
Suite 2222
Cleveland, Ohio 44113
FGallucci@pglawyer.com

-and-

NAPOLI SHKOLNIK, PLLC

/s/ Hunter J. Shkolnik
Hunter J. Shkolnik
Joseph L. Ciaccio
Salvatore C. Badala

NAPOLI SHKOLNIK, PLLC
400 Broadhollow Road – Suite 350
Melville, New York 11747

-and-

THRASHER DISMORE & DOLAN LPA

/s/ Leo M. Spellacy, Jr.
Leo M. Spellacy, Jr. Esq. (0067304)
1111 Superior Avenue, Suite 412
Cleveland, OH 44114
Telephone: 216-225-5431
Fax: 216-255-5450
lspellacy@tddlaw.com

-and-

SCOTT ELLOT SMITH LPA

/s/ Scott Elliot Smith
Scott Elliot Smith (003749)
5003 Horizons Dr. Ste. 200
Columbus Oh. 43220
614-846-1700
614-486-4987 Fax
ses@sestriallaw.com

-and-

DEMER & MARNIELLA, LLC

/s/ James A. Marinella
James A. Marniella, Esq. (0073449)
2 Berea Commons, Suite 200
Berea, OH 44017
Telephone: 440-891-1644
Fax: 440-891-1644

Counsel for the County of Lake

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 15th day of May, 2020, I electronically filed the foregoing as a Sealed Document with the Clerk of Court by using the CM/ECF System. The foregoing will be served on counsel of record subject to the applicable Protective and Confidentiality Orders. A redacted version of the foregoing will be filed in the CM/ECF system and will be served upon counsel of record.

By: /s/ Hunter J. Shkolnik